

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.

**This Page Blank (uspto)**



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61B	A2	(11) International Publication Number: WO 97/32514 (43) International Publication Date: 12 September 1997 (12.09.97)
<p>(21) International Application Number: PCT/US97/03320</p> <p>(22) International Filing Date: 3 March 1997 (03.03.97)</p> <p>(30) Priority Data: 08/610,619 4 March 1996 (04.03.96) US 08/692,992 6 August 1996 (06.08.96) US</p> <p>(71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).</p> <p>(72) Inventors: FLOM, James, R.; 2557 Park Boulevard #L102, Palo Alto, CA 94306 (US). MANGOSONG, Lorraine; 2994 Cheswycke Terrace #352, Fremont, CA 94536 (US). PETERS, William, S.; 59 Brighton Road, Unit 2, Elwood, VIC 3184 (AU). GARRISON, Michi; 2325 Casa Bona Avenue, Belmont, CA 94002 (US). FRISCHMEYER, Karen; 775 Chimalus Drive, Palo Alto, CA 94306 (US). KRIER, Jeffrey; 651 Avenue Cabrillo, El Granada, CA 94018 (US). MUELLER, Richard, L.; 2305 Cypress Point, Byron, CA 94514 (US). BOYD, Stephen, W.; 333 Palomar Drive, Redwood City, CA 94062 (US).</p> <p>(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend &amp; Crew L.L.P., 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: RETRACTOR FOR PROVIDING SURGICAL ACCESS AND SUTURE ORGANIZER</p> <p>(57) Abstract</p> <p>A flexible, length-adjustable suture organizer coupled to a retractor having a number of flexible straps. The straps are tensioned to retract tissue while the suture organizer is used to retain sutures extending through an opening created by the retractor. The retractor includes a holder which retains the suture organizer.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

5                   **RETRACTOR FOR PROVIDING SURGICAL ACCESS**  
                    **AND SUTURE ORGANIZER**

Field of the Invention

10           The present invention relates to suture organizers  
and retractors for soft tissues and methods for their use to  
provide surgical access into body cavities.

          Coronary artery disease remains the leading cause of  
morbidity and mortality in western societies. Coronary artery  
disease is manifested in a number of ways. For example,  
15   disease of the coronary arteries can lead to insufficient  
blood flow resulting in the discomfort and risks of angina and  
ischemia. In severe cases, acute blockage of coronary blood  
flow can result in myocardial infarction, leading to immediate  
death or damage to the myocardial tissue.

20           A number of approaches have been developed for  
treating coronary artery disease. In less severe cases, it is  
often sufficient to treat the symptoms with pharmaceuticals  
and lifestyle modification to lessen the underlying causes of  
disease. In more severe cases, the coronary blockage can  
25   often be treated endovascularly using techniques such as  
balloon angioplasty, atherectomy, or stents.

          In cases where pharmaceutical treatment and/or  
endovascular approaches have failed or are likely to fail, it  
is often necessary to perform a coronary artery bypass graft  
30   procedure using open surgical techniques. Such techniques  
require that the patient's sternum be opened and the chest be  
spread apart to provide access to the heart. A source of  
arterial blood is then connected to a coronary artery  
downstream from an occlusion, while the patient's heart is  
35   maintained under cardioplegia and circulation is supported by  
cardiopulmonary bypass. The source of blood may be a vessel  
taken from elsewhere in the body such as a saphenous vein or  
radial artery, or an artery in the chest or abdomen such as

the left or right internal mammary artery or the gastroepiploic artery. The target coronary artery can be the left anterior descending artery, right coronary artery, circumflex artery, or any other coronary artery which might be narrowed or occluded.

While very effective in many cases, the use of open surgery to perform coronary artery bypass grafting is highly traumatic to the patient. The procedure requires immediate post-operative care in an intensive care unit, a total period of hospitalization of seven to ten days, and a recovery period that can be as long as six to eight weeks.

Recently, it has been proposed to utilize minimally invasive surgical techniques and procedures to perform coronary artery bypass grafting and other traditionally open-chest cardiac surgical procedures. A wide variety of laparoscopic, arthroscopic, endovascular, and other minimally invasive surgical therapies have been developed. These procedures generally utilize trocars, cannulas, catheters, or other tubular sheaths to provide an artificial lumen, through which specialized tools are inserted and manipulated by the surgeon.

An exemplary minimally invasive bypass method is described in U.S. Patent No. 5,452,733, assigned to the assignee of the present application, the full disclosure of which is herein incorporated by reference. This exemplary coronary artery bypass method relies on viewing the cardiac region through a thoracoscope and endovascularly portioning the patient's arterial system at a location within the ascending aorta. The bypass procedure is performed under cardiopulmonary bypass and cardioplegia, while the coronary anastomoses are formed within the chest cavity through the use of a plurality of trocar sheaths placed between the patient's ribs.

Although thoracoscopic methods hold great promise for decreasing morbidity and mortality, cost, and recovery time when compared to conventional open surgical coronary bypass procedures, these methods could benefit from still further improvements. In particular, the surgical access

provided by known trocar sheaths has not been optimally adapted for performing thoracoscopic coronary artery bypass. The length of conventional trocar sheaths and the small size of their lumens limits the maneuverability of surgical instruments and inhibits the ability to look directly into the chest cavity while an instrument is positioned through the trocar sheath.

It would therefore be desirable to provide improved surgical access devices and methods for their use in performing less invasive coronary artery bypass grafting and other thoracoscopic surgical procedures, and minimally invasive surgical procedures in general. It would be particularly desirable if such devices and techniques provided atraumatic retraction of soft tissue of the chest wall to create the largest possible surgical access window without resorting to a sternotomy or gross retraction or removal of the ribs. Preferably, such improved surgical access devices and methods would provide a flexible access lumen which could be positioned and sized to meet the individual patient's physiology. The devices should have minimum height so as to extend as little as possible from the inner or outer surfaces of the chest wall. It would further be desirable if such access devices and methods allowed direct or magnified viewing of the internal procedure from outside the patient body, thereby decreasing the time and trauma associated with the internal surgical procedure, and increasing overall efficacy over both open surgical procedures and minimally invasive surgical procedures performed through the small trocar sheaths which have been relied on in the prior art.

Conventional thoracoscopic techniques are described in Landreneau et al. (1992) *Ann. Thorac. Surg.* 54:800-807. Conventional open surgical procedures for performing coronary artery bypass grafting are described in Kirkland and Barratt Boyes, *Cardiac Surgery*, John Wiley and Sons, Inc., New York, 1993 (2nd Ed.).

A minimally invasive method for performing coronary artery bypass grafting using an anterior mediastinotomy, including excision of either the third or fourth costal

cartilage, was described by Robinson et al. in *J. Card. Surg.* (1995) 10:529-536.

U.S. Patent No. 5,391,156 describes a flexible endoscopic surgical port having a tubular body, the outer end of which is optionally divisible into a plurality of flaps, thereby matching the length of the tubular body with the thickness of a body wall. A retainer ring engages the flaps to hold the port axially, while the hoop strength of the tubular body holds the adjacent tissue in a retracted position. U.S. Patent No. 4,274,398 describes a surgical retractor having elastic tubes which hold hooks under radial tension from a notched frame. U.S. Patent Nos. 4,430,991, and 4,434,791, describe similar surgical retractor frames for use with hooked members. Such a system is commercially available under the trade name LoneStar Retractor System™.

A surgical drape having a central open ring for insertion over known surgical retractors is commercially available from Becton Dickinson of Franklin Lakes, New Jersey under the tradename Vidrape®. Relevant minimally invasive methods and devices for heart surgery are described in U.S. Patent No. 5,452,733; U.S. Patent Application Serial No. 08/163,241, filed December 6, 1993; U.S. Patent Application Serial No. 08/194,946, filed February 11, 1994; U.S. Patent Application Serial No. 08/227,366, filed April 13, 1994; and U.S. Patent Application Serial No. 08/486,941, filed June 7, 1995, the full disclosures of which are incorporated herein by reference.

The present invention is also directed to devices and methods for performing minimally invasive valve procedures. In particular, the present invention is directed to suture organizers and retractors which can be used in minimally invasive valve repair and replacement procedures.

In conventional valve repair and replacement procedures, the sternum is cut and the ribs are spread apart with a rib spreader. A rigid suture organizer is then positioned over the rib spreader to organize sutures used to attach the replacement valve or annuloplasty ring to the patient's valve annulus. An example of a rigid suture



organizer and a rib spreader are shown in U.S. Patent No. 4,492,229 to Grunwald.

#### SUMMARY OF THE INVENTION

5           In a first aspect, the present invention provides a retractor for providing surgical access to a body cavity of a patient through a passage in tissue. The retractor comprises an anchoring frame having an upper surface, a lower surface, and an opening therethrough which defines an axial axis. The  
10   anchoring frame is positionable through the passage into the body cavity. A flexible tensioning member is attached to the anchoring frame and extendable from the frame out of the body through the passage. The tensioning member is selectively  
15   tensionable to spread the tissue radially outwardly from the axial axis. Hence, it is the tension imposed on the flexible tensioning member which effects retraction of the tissue, rather than relying on the structural integrity of a tubular structure such as a trocar sheath.

          Generally, an attachment mechanism on the tensioning  
20   member maintains tension so as to retract tissue from the passage. Hence, the tensioning member need only be capable of withstanding and transferring the tension imposed by the attachment mechanism, there being no need for a rigid  
25   structure having sufficient hoop strength to maintain the tissue in the retracted position. The resulting surgical access window need not be compromised by any rigid lumen wall or rigid blade-type structure, and the retraction load is distributed atraumatically over a wide area of the tissue by the flexible tensioning member.

30           Preferably, the anchoring frame will have a narrow profile configuration for insertion through an incision into the body cavity, and will be expandable to a wide profile configuration once inside the body cavity. The frame may  
35   comprise a variety of collapsible and expandable structures, including a ring of resilient material which expands to the large configuration when released. The tensioning member is preferably formed of a plurality of elongate tabs or strips of cloth, tape, cord, or strap material, ideally comprising an

absorbent material such as gauze so as to absorb any fluids released by the tissue bordering the passage. Alternatively, an elastomeric or semi-elastomeric sheet or strip may be used.

In another aspect, the present invention provides a retractor for providing surgical access into a chest cavity defined by a plurality of ribs. The ribs are separated by intercostal tissue and an intercostal width. The retractor comprises an anchoring frame which is insertable into the chest cavity through a passage between two ribs, the frame having an opening. A flexible tensioning member extends from at least two opposing sides of the opening in the frame. The tensioning member is able to extend out of the chest cavity through the passage when the frame is within the chest cavity and the opening in the frame is generally aligned with the passage. The tensioning member may be tensioned to spread the intercostal tissue outward toward the two ribs. Such a retractor is particularly well suited for forming an anterior mediastinotomy or small thoracotomy for use in a less invasive coronary artery bypass grafting procedure or other cardiac procedure.

Generally, an attachment mechanism on the tensioning member maintains outward radial tension from outside the patient to hold the intercostal tissue in a retracted position. In some embodiments, the attachment mechanism comprises an adhesive disposed on the tensioning member to facilitate attachment to an outer surface of the patient's chest. Optionally, a surgical film may be adhered to the exterior of the chest surrounding the passage to facilitate adherence of the tensioning member to the chest wall. In alternative embodiments, the attachment mechanism comprises a plurality of clasps or other coupling devices disposed about an outer ring structure which is positioned outside the body cavity.

In yet another aspect, the present invention provides an illuminated retractor for providing surgical access to a body cavity of a patient through a passage in tissue. The retractor comprises an internal anchor having an opening, the anchor being insertable through the passage and

into the body cavity. A tissue restraining structure extends proximally from the internal anchor for holding the passage open sufficiently to provide direct visualization of the internal body cavity from outside the patient. Typically, an external anchor is spaced proximally from the internal anchor on the tissue restraining member. An illuminating device is disposed adjacent to the opening in the internal anchor to facilitate visualization of the cavity through the open passage.

In yet another aspect, the present invention provides a tissue retractor system for providing surgical access through an incision in tissue to a body cavity of a patient. The system generally comprises a retractor and a retractor delivery device. Specifically, the retractor comprises an anchoring frame having an opening, wherein the frame is restrainable into a narrow profile to facilitate insertion of the frame into the body cavity. The frame is expandable into a wide profile when inside the body cavity. A flexible tensioning member extends from the frame adjacent to the opening and is selectively tensionable to retract the tissue adjacent the incision, and is adapted to be secured in tension outside the body cavity.

The retractor delivery device comprises a device body having distal and proximal ends, and a pair of inward facing surfaces near the distal end which restrain a frame of the retractor therebetween to a small profile. A handle supports the inward facing surfaces from a proximal end. An actuator may be provided on the handle to effect expansion of the frame within the body cavity.

The present invention also provides a method for retracting tissue to temporarily widen a penetration into a body cavity, the method comprising positioning an anchoring frame against a tissue surface within the body cavity adjacent to the penetration so that an opening in the frame is aligned with the penetration. The frame has a width across the opening which is wider than the penetration. A tissue restraining member extending from the frame out of the body

cavity through the penetration is tensioned so as to urge the tissue adjacent the penetration outwardly.

In a further aspect, the present invention provides a method for performing surgery on a patient's heart, the heart being disposed within a chest cavity defined by a plurality of ribs, the ribs being separated by intercostal tissue and an intercostal width. The method comprises inserting an anchoring frame into the chest cavity through an incision between two ribs, wherein the frame has an opening and a width across the opening wider than the intercostal width. Tension is then imposed on a plurality of flexible tabs extending from the frame adjacent to the opening so as to widen the incision. Surgery is then performed on the heart using instruments positioned through the widened incision.

In another aspect of the present invention, a flexible suture organizer is provided for organizing sutures in a surgical procedure such as a valve repair or replacement procedure. The flexible suture organizer permits the surgeon to deform the suture organizer to a shape which generally conforms to the shape of the patient so that the suture organizer does not interfere with the surgical procedure.

The suture organizer of the present invention is particularly useful for the minimally-invasive valve procedures described in U.S. Patent Application Serial No. 08/163,241 which is incorporated herein by reference. The valve repair and replacement procedures described in U.S. Patent Application Serial No. 08/163,241 use smaller openings in the patient which are positioned lateral of the traditional median sternotomy. As such, the openings in the patient are positioned on more curved parts of the patient's body. The flexible suture organizer of the present invention may be conformed to these curved portions of the patient's body so that the suture organizer does not interfere with the surgical procedure.

In another aspect of the present invention, the suture organizer also has a length-adjusting mechanism for adjusting the length of the suture organizer. The length adjusting mechanism is particularly useful when performing

minimally invasive valve repair and replacement procedures since the opening in the patient may vary in size depending upon the particular patient. The length-adjusting mechanism permits the surgeon to select an appropriate suture organizer  
5 size for the patient.

In another preferred embodiment, the suture organizer is formed with a number of sections which are coupled together by releasable connections. The surgeon may select the appropriate number of sections and the appropriate  
10 shape of the suture organizer by adding or removing sections as necessary.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a retractor system according to the principles of the present invention, the system including a  
15 retractor and an associated delivery device.

Fig. 2 is a cutaway view of the retractor of Fig. 1 as used for retracting intercostal tissue from between ribs to provide access to the chest cavity.

20 Fig. 2A is a cutaway view of a surgical instrument positioned through a typical known trocar sheath.

Fig. 2B is a cutaway view of a surgical instrument positioned through the retractor of Fig. 1, showing the increased angulation and maneuverability provided by the  
25 surgical access of the present invention.

Fig. 3 shows the retractor system of Fig. 1 with the retractor restrained in a small configuration by the delivery device.

30 Figs. 4-6 illustrate a method of using the retractor system of Fig. 1 to provide surgical access to a body cavity.

Figs. 6A-6C illustrate alternative delivery devices for use with the retractor of Fig. 1.

35 Figs. 6D-G illustrate an alternative retractor having grommets and an associated delivery device, according to the principles of the present invention.

Figs. 7-9A show alternative embodiments of tissue retractors according to the principles of the present invention.

Figs. 10A-10E illustrate an alternative embodiment of a retractor system according to the principles of the present invention and a method for its use.

5 Fig. 10F illustrates an alternative outer ring structure for use with the retractor of Fig. 10A.

10 Figs. 11A and 11B illustrate a retractor having illuminating fiberoptics disposed about an internal anchoring ring to provide both illumination and access to an internal body cavity, according to the principles of the present invention.

Figs. 12A and 12B illustrate a method for using the retractor of Fig. 1 for coronary artery bypass grafting, according to the principles of the present invention.

15 Fig. 13 illustrates a method of retracting tissue during treatment of cardiac valve disease, according to the principles of the present invention.

Fig. 14 illustrates a flexible suture organizer for organizing sutures during a valve repair or replacement procedure.

20 Fig. 15 illustrates suture holders of the flexible sutures organizer of claim 14.

Fig. 16 illustrates a length-adjusting mechanism for the suture organizer of Fig. 14.

25 Fig. 17 illustrates another preferred flexible suture organizer having a manually separable connection.

Fig. 18 illustrates the relatable connection for the flexible suture organizer of Fig. 17.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

30 The devices and methods of the present invention are suitable for providing access for a variety of surgical procedures within the cavities of the body. Such access is particularly advantageous during minimally invasive and less invasive surgical procedures in which surgical instruments are introduced through an access window provided by the retraction  
35 of tissue.

The present retraction methods and devices will find particular use where direct visualization into a body cavity

through a percutaneous penetration facilitates the surgical procedure. Alternatively, an endoscope, laparoscope, thoracoscope, or other visualization device may be inserted through such an access window for telescopic or video-based visualization. Additionally, tissues and/or organs may be temporarily extended through the access window to allow external manipulation during therapy. The retraction methods and devices of the present invention will thus find applications in providing surgical access to the pelvis, abdomen, thorax, and other body cavities, to facilitate surgical intervention on the gall bladder, colon, reproductive organs, kidneys, liver, stomach, heart, lungs, and other body structures.

The present invention will find its most immediate application in less-invasive surgery of the heart, particularly in less-invasive coronary artery bypass grafting, less-invasive valve repair and replacement, and other cardiac procedures. Surgical access windows provided by the flexible tensioning member of the retractor of the present invention will easily flex to adapt to the minimally invasive tools used in less invasive bypass procedures, thereby allowing these tools to be manipulated more easily and used at a wider range of angles than could be accommodated by the rigid and semi-rigid trocar sheaths and conventional rigid retractors of the prior art. By utilizing tension in a flexible strap or tab, the intercostal tissue between ribs may be atraumatically retracted as widely as possible without inflicting a gross displacement of the ribs and the resulting patient trauma. However, where greater access is desired and/or required, the retraction methods and devices of the present invention may also be used in combination with the excision of costal cartilage or even a partial sternotomy or small thoracotomy to maximize the size of the open access port.

Referring now to Fig. 1, a retraction system 10 comprises a retractor 12 and a delivery device 14. Retractor 12 includes an anchor ring 16 from which a plurality of flexible tabs 18 extend. An adhesive is coated over a portion

of each of tabs 18, and a backing strip 20 removably covers the adhesive to facilitate handling the retractor.

Anchoring ring 16 may be either rigid or flexible, but preferably comprises a resilient material biased to form an annular ring shape. A variety of other frame shapes might also be used, including C-shaped, U-shaped, rectangular, elliptical, triangular, parabolic, and optionally including articulated or living hinge joints. In any event, the anchoring frame will have at least two sections separated by an opening or gap such that the frame may be placed through a passage in a body wall into a body cavity and the two sections positioned on either side of the passage with the opening therebetween aligned with the passage. The anchoring ring may optionally be made of a relatively high strength polymer such as Delrin™, nylon, high density polyethylene, and the like. Preferably, the anchoring ring comprises a high strength biocompatible alloy, ideally being a superelastic alloy such as Nitinol®. Such an alloy ring may be formed by welding, crimping the joint with a stainless steel tube, butt jointing with heat shrink tubing, or the like, the ring preferably having a diameter between about 10 mm and 9 cm. The exemplary annular superelastic alloy anchoring ring may be readily compressed to a small configuration for insertion, will readily expand to the large open configuration shown in Figs. 1-2 once inside the body cavity, and will withstand the compressive loads imposed by flexible tabs 18 during retraction of tissue as described hereinbelow.

The axial dimension of anchoring ring 16 is preferably minimized to provide maximum open working area within the body cavity and to provide maximum maneuverability of instruments positioned through it. In an exemplary embodiment, the anchoring ring has an axial thickness of less than about 20 mm, and preferably less than about 10 mm.

Flexible tabs 18 preferably comprise elongate strips of an absorbent material such as gauze, cloth tape, or the like. Such gauze tabs may be easily looped over anchoring ring 16 and sutured, sewn, adhesively bonded, heat sealed, or welded to themselves. Alternatively, tabs 18 may be directly



adhesively bonded to anchoring ring 16, may be molded into the anchoring ring, or may have the anchoring ring woven into the tab material. Use of an absorbent material allows the flexible tab to absorb blood and other fluids which might otherwise seep from the retracted tissue into the body cavity. Where absorbency is less important, flexible tabs 18 may be an elastomer or a flexible, deformable or resilient metal.

The adhesive behind backing strips 20 will generally comprise a medical grade adhesive suitable for attachment to human skin or to paper, cloth, metal or plastic surfaces, such as an acrylate or other suitable adhesive. Conveniently, attachment may be facilitated by the use of a plastic film adhered to the patient's chest prior to insertion of the retractor, allowing backing strips 20 to be affixed securely to the plastic film.

Delivery device 14 generally includes a distal end 22 and a proximal end 24. The distal end includes inward facing surfaces 25 which releasably restrain the anchoring ring in a small profile configuration, while the proximal end 24 includes a handle 27 for manipulation of these inward facing surfaces. Handle 27 comprises a pair of finger loops which may be actuated by passing the thumb and a finger therethrough and separating and/or bringing together the thumb and finger. Arms 29 extend distally to support each of the inward facing surfaces, the arms being hinged to form jaws 31 which widen or narrow the distance between inward facing surfaces 25 as handle 27 is actuated. Preferably, arms 29 are generally U-shaped as shown, extending distally, turning outward, and returning proximally to inward facing surfaces 25. Optionally, a releasable detent or ratchet (not shown) between the handles helps restrain inward facing surfaces 25 at their closest proximity.

A particularly advantageous use of the retractor of Fig. 1 for accessing the chest cavity by retracting the soft intercostal tissue between ribs will be described with reference to Fig. 2. A chest wall W is defined by a plurality of ribs R separated by intercostal tissue T. Anchoring ring 16 of retractor 12 is shown inserted through a passage P

through the chest wall. As used herein, a passage means any opening, puncture, wound or incision through tissue to a body cavity, whether open or closed. Hence, passage P may comprise an incision, a mediastinotomy, thoracotomy, or other opening  
5 formed by the cutting or removal of tissue, bone, or cartilage, a percutaneous opening through tissue, or the like. In any event, tabs 18 extend from the anchoring ring 16 outward through passage P. An upper surface 17 of anchoring ring 16 is placed against an inner surface S of chest wall W,  
10 while a lower surface 19 is oriented into the chest cavity C.

As tabs 18 are highly flexible and formed from separate elongate strips, they retract little or no tissue from the passage P when loose. However, when tension is applied to tabs 18, that tension is transmitted along the tab  
15 to act in a radial outward direction 26 against the tissue which borders the passage P. The transmission of tension through the flexible tabs results in a retraction of tissue from both outside and inside the body cavity, without interrupting the passage with a rigid trocar sleeve or other  
20 rigid retracting structure. Adhesive 28 disposed on tabs 18 conveniently allows the tissue to be held in the retracted position by affixing the tabs to the surface of the chest or to another external structure.

Access to the interior of body cavity C is thus  
25 provided through the passage P by retracting tissue so as to form an open window. Tabs 18 are radially opposed, so that opposing radial tensions 26 help to hold anchoring ring 16 in alignment with the open window, and also so that tissue is retracted in opposite directions. Thus, access to the body  
30 cavity is provided through an opening 30 in anchoring ring 16, which is preferably larger than the open passage to prevent any interference, and preferably wider than an intercostal width between adjacent, uncontracted ribs.

The improved access and visualization provided by  
35 the retractor of the present invention is seen most clearly in Figs. 2A and 2B. Known trocar sheath 2 has a structural lumen 4 which must have walls of sufficient rigidity and thickness to retract intercostal tissue T. The length of lumen 4 is

significantly greater than the thickness of chest wall W to ensure that the lumen remains open when trocar sheath 2 is canted by a moderately angled surgical tool 6. The length of lumen 4 will also often be increased to allow trocar sheath 2 to accommodate chest walls of varying thickness, further decreasing unimpeded angulation and maneuverability of surgical tool 6. Clearly, direct visualization of an internal procedure through lumen 4 of trocar sheath 2 would be highly problematic, even where surgical tool 6 is limited to the moderate angle shown.

In contrast to known trocar sheaths, retractor 12 provides a surgical access window that accommodates less invasive surgical implement 3 at a large angle relative to axial axis A, and with improved maneuverability and visualization. Tension in tabs 18 retracts intercostal tissue T from passage P, and also pulls anchoring ring 16 firmly against the inner surface S of chest wall W. Not only does this avoid interference from the ring frame, but the tension of tabs 18 will actually compress the thickness of chest wall W adjacent passage P, further increasing the range of motion of implement 3. Finally, if even higher angles are required, the surgeon need only apply the force necessary to locally displace the tissue adjacent the angled tool, as the flexible tabs do not have a structural lumen which resists distortion. It can also be seen in Fig. 2B that visibility through a surgical access window provided by retractor 12 is substantially enhanced, particularly from viewpoints which are at a substantial angle from axial axis A of anchoring ring 16.

The deployment of retractor 12 using delivery device 14, will be explained with reference to Figs. 3-6. Preferably, delivery device 14 is inserted through opening 30 and jaws 31 are opened to align channels 34 with ring 26. Ring 26 is positioned within channels 34 adjacent to inward-facing surfaces 25. The handle is then manipulated so that inward facing surfaces 25 engage the anchor ring to squeeze anchor ring 16 into the elongate narrow profile configuration shown in Figs. 3 and 4. Typically, delivery device 14 will realizable maintain the anchor ring in the narrow profile

configuration during positioning. Anchoring ring 16 is then inserted through incision I, preferably in an edgewise orientation as shown in Fig. 4. As used herein, an edgewise orientation means that the axial axis of anchoring ring 16 is at an angle substantially less than 90° relative to, and preferably parallel to, the surface of the body on which incision I is disposed.

Release of anchor ring 16 within the body cavity is most clearly understood with reference to Figs. 2A and 5. As shown in Fig. 2A, the anchoring ring may be expanded radially within the body cavity by moving inward-facing surfaces 25 away from one another. The delivery device is withdrawn by first displacing it distally beyond detent 36. Jaws 31 are then closed and the delivery device is withdrawn from incision I.

Prior to tensioning, opposed tabs 18 have little effect on the incision I. Conveniently, the tabs may be simply pulled outward by hand to tension tabs 18 and thereby retract the tissue adjacent to the incision. Anchoring ring 16 is drawn into engagement with the interior surface S of the chest wall (as best seen in Fig. 2). When the tissue is sufficiently retracted, backing strips 20 are removed and the tabs affixed in place using the exposed adhesive, as illustrated in Fig. 6. The resulting open window 38 is of maximum size without any significant retraction of the ribs to accommodate various types and sizes of instruments and facilitating a high degree of angulation and motion of such instruments. Furthermore, the chest wall tissue is compressed between the tabs 18 and ring 16, minimizing chest wall thickness to enhance instrument maneuverability. This contrasts with conventional tubular ports, trocar sleeves, and other rigid retractors which have a significant length extending both into and outside of the body cavity, hampering manipulation of instruments.

Referring now to Figs. 6A and 6B, an alternative delivery device 31 includes an inner support member 35 and a slidable outer member 37 having inward facing surfaces 33. Outer member 37 may be retracted proximally relative to an

inner support member 35 to allow ring 16 to expand resiliently when released. The inner support member is then withdrawn from the expanded ring. A portion of tab 18 adjacent inward facing surface 33 is removed from Fig. 6A for clarity.

5 Referring now to Fig. 6C, a still further alternative delivery device 41 includes fixed inward facing surfaces 43 on a distal bracket 45. Fixed surfaces 43 are defined by a slot 47 in bracket 45, the slot accepting a pair of opposing tabs 18. Tensioning of the tabs 18 which pass  
10 through slot 47 collapses anchoring ring 16 to the narrow profile configuration during insertion. Releasing the tension from outside the patient allows the anchoring ring 16 to expand resiliently.

A still further alternative delivery device 61 will  
15 be described with reference to Figs. 6D-G. This embodiment makes use of a retractor having tabs 63 with openings which are reinforced with grommets 65. The grommets facilitate holding the tabs with pin 67 of actuator 69. The actuator is upwardly slidable relative to a pair of rollers 71 mounted to  
20 a handle 73. Tabs 63 are threaded around rollers 71 and grommets 65 placed over pins 67. As seen most clearly in the front view of Fig. 6F, grasping handle 73 and drawing the actuator in the upward direction indicated will tension the tabs and compress ring 16. Rollers 71 may optionally rotate,  
25 or the tabs may slide over the roller's rounded surface. In either case, the distance between the rollers need not change. Hence, the portion of each roller which is adjacent to the other roller defines an inward facing roller surface 75; and the anchoring ring is restrainable in the narrow configuration  
30 by these inward facing roller surfaces when the tab is held under tension by pin 67. Alternatively, the grommets maybe disposed on separate tethers attached to the ring, so that the tabs are used only for retraction of tissue.

Referring now to Fig. 7, an alternative embodiment  
35 of a retractor according to the principles of the present invention comprises an internal anchoring ring 46 and a tissue restraining member comprising a single-piece sheet 48, which may be flat, bowl-shaped or tubular, preferably comprising a

thin semi-elastic polyethylene or urethane material. Adhesive backing 44 disposed on opposed extended tab 49 provides an attachment mechanism to restrain the tissue in the retracted position.

5 Referring now to Fig. 8, a still further alternative embodiment of the present retractor 50 comprises an outer ring 54, an anchoring ring 56, and tabs 58 coupled therebetween. Expansion mechanism 60 allows the diameter of outer ring 54 to be increased when knob 62 is turned, thereby  
10 tensioning tabs 58 when the anchor ring is in position. In an exemplary configuration, outer ring 54 is a split ring with overlapping portions 54a, 54b. Expansion mechanism 60 comprises a clamp for clamping overlapping portions 54a, 54b in position; e.g., knob 62 may be a set screw which engages  
15 overlapping portion 54a and urges it against portion 54b. Alternatively, expansion mechanism 60 may mechanically expand ring 54, e.g., by a pinion gear attached to knob 62 which engages a series of teeth along one of overlapping portions 54a, 54b so as to expand ring 54 when the knob is turned.

20 In a further embodiment, shown in Fig. 9, a balloon retractor 60 includes an outer balloon ring 64, an anchor ring 66, and a tubular elastomeric tissue restraining member 68 extending therebetween, as seen retracting tissue in chest wall W. Balloon ring 64 is generally elastomeric or semi-  
25 elastomeric, and preferably comprises baffles 72 to give the balloon greater structural integrity and stiffness. The size of the balloon ring (and hence the tension on restraining member 68) may be varied using inflation pump 74 and temporarily fixed with stopcock 76. As the diameter of the  
30 balloon ring expands under greater inflation pressure, tab 68 increasingly retracts tissue between ribs R.

Referring now to Fig. 9A, a still further embodiment of the present retractor 109 includes a polymeric anchoring ring 111 and a plurality of adhesive backed flexible tabs 105.  
35 Polymeric anchoring ring 111 includes rigid sections 111A separated by opposed living hinges 107, preferable formed by locally tapering the thickness of the ring material. Optionally, the anchoring ring is machined from nylon,

Delrin™, a high density polyethylene, or another relatively high strength polymer. Living hinge 107 facilitates compressing the prosthesis into a narrow diameter configuration by promoting localized bending, and adhesive backed tabs 105 may optionally be attached to the ring by wrapping the tab about the ring so that the tab adhesive adheres to the ring surface. Living hinges 107 may alternatively comprise pin joints or other hinges to provide pivotal motion between sections 111A.

Referring now to Fig. 10A, a still further embodiment of the present retractor 81 comprises an anchoring ring 82, tabs 84, and an outer ring 86. Tabs 84 have a tissue restraining portion 98 from which tethers 96 extend. Tethers 96 pass through slots 99 in outer ring 86, the tethers tensioning tissue restraining portions 98 so as to retract tissue from the passage. Conveniently, slots 99 are provided with catches, clamps, or ratchets 100 to engage each tether 96 so as to restrain the tissue in the retracted position. These ratchets facilitate expansion of the access window by manually pulling tethers 96 relative to outer ring 86.

Referring now to Figs. 10B-10E, a particularly advantageous retractor system 80 comprises retractor 81 and a delivery device including an obturator 88 having a longitudinal channel 89 with inward facing surfaces 90 which restrain the anchor ring therebetween. An actuation handle 92 is located on the proximal portion of the delivery device.

Once the obturator is inserted through the chest wall W, depressing button 94 of handle 92 advances a push rod 95 distally to expel anchor ring 82 distally from the obturator. The individual length of tabs 84 is selected to promote alignment between the anchoring ring opening and the passage through the tissue. Tabs 84 again include a tissue restraining portion 98 from which tethers 96 extend. Tethers 96 initially extend from tabs 84 through slots 99 in outer ring 86, and back to the proximal handle 92 of the delivery device. Thus, proximally retracting obturator 88 relative to the outer ring 86 pulls anchor ring 82 against chest wall W and tensions tethers 96. Tethers 96 are attached to proximal

handle 92 by anchors 101 which are held within apertures 103 in proximal handle 92, as shown in Fig. 10D. Rotation of knob 98 of proximal handle 92 releases anchors 101 from apertures 103 to decouple tethers 96 therefrom, allowing the delivery device to be removed from the retractor, leaving an open access port through the retractor as shown in Fig. 10A.

Referring now to Fig. 10F, an alternative outer ring 102 includes a plurality of temporary suture retainers 104 useful in maintaining suture organization in surgical procedures that require a large number of sutures. Retainers 104 may comprise a plurality of radially-oriented slots between 4 and 30 in number configured to frictionally retain a suture thread placed in the slot. Alternatively, retainers 104 may be hooks, eyelets, clamps, cleats, or the like.

The retractors of the present invention are particularly advantageous when used with direct visualization through an open window, resulting in faster and more cost efficient less invasive surgical procedures. Such direct visualization reduces or avoids the necessity to resort to thoroscopes and other remote imaging modalities. However, this elimination of the scope from the interior body cavity may also eliminate the primary source of illuminating light, the illumination fiber optics which are generally provided with such scopes. Therefore, the present invention further provides illuminated retractors, an exemplary embodiment being illustrated in Figs. 11A and 11B.

Illuminating retractor 110 includes an anchoring ring 112 and a plurality of tabs 114 as described above, and also includes a plurality of illuminating optical fibers 116 disposed about the anchoring ring and having distal ends 117 pointing distally into the body cavity from the lower surface of anchor ring 112. Advantageously, optical fibers 116 extend independently in the proximal direction along the tabs, minimizing any reduction in the size of the opening in the body wall. These independent fibers are then combined together in a cable 119 a short distance from ring 112 and attached to one or more optical couplers 118. Cables 119 may or may not be mounted to one or more tabs 114.



The illuminating ends 117 of optical fibers 116 are generally oriented distally into the body cavity, and may be molded into the anchoring ring, bonded onto an inner or outer surface of the anchoring ring, or may terminate along tabs 114 adjacent to the anchoring ring. Similarly, the dispersed fiberoptics along tabs 114 might be woven into a textile tab, imbedded within a polymer tab with reinforcing or malleable members for optimal light positioning, or be bonded on an inner or outer surface of the tab. Advantageously, the dispersion of the optical fibers across the tab not only minimizes the profile of the fibers, but also helps to maintain the flexibility of the tabs.

The use of retractor 12 during a coronary artery bypass grafting procedure is illustrated in Figs. 12A and 12B. As more fully explained in U.S. Patent No. 5,452,733, previously incorporated herein by reference, an exemplary bypass procedure involves harvesting of the internal mammary artery IMA and joining it with the diseased coronary artery, here the left anterior descending coronary artery LAD. Optionally, a plurality of conventional trocar sheaths, may be used in combination with the retractor 12 of the present invention. Alternatively, the present method for coronary artery bypass grafting may be performed entirely through surgical access windows provided by one or more retractors according to the present invention.

Internal mammary artery IMA may be joined to incision 122 in the coronary artery LAD by a variety of conventional techniques, including suturing, laser welding, tissue gluing, microstapling, and the like. When conventional suturing techniques are used, a length of suture 124 having a needle 126 on at least one end may be manipulated using forceps 128 either inside the chest cavity, or outside the chest cavity directly adjacent retractor 12. In either case, forming the anastomoses is greatly facilitated by the high degree of instrument mobility and by the direct visualization of the procedure provided by retractor 12.

Referring now to Fig. 13, a retractor 130 similar to the embodiment shown in Fig. 10A and having suture organizing

outer ring 102 as illustrated in Fig. 10F is particularly advantageous for use in a less invasive surgical procedure for repair or replacement of a heart valve, for example a mitral valve MV via the left atrium LA. Access to the heart H through the window provided by retractor 130, and/or through trocar sheaths 120 is improved by deflating right lung L. As more fully explained in copending Patent Application Serial No. 08/485,600, filed June 7, 1995, the full disclosure of which is incorporated herein by reference, a valve prosthesis 131, such as a mechanical heart valve or annuloplasty ring, may be positioned through retractor 130 into the heart and secured at the native valve position to repair or replace the native valve. A plurality of sutures 132 are used to secure the prosthesis in the heart, and each suture may be drawn out of the chest and retained in suture organizing outer ring 102 as described above in connection with Fig. 10F to prevent tangling and disorganization.

In yet another aspect of the present invention, a flexible, length-adjustable suture organizer 200 is provided as shown in Figure 14. The suture organizer 200 is preferably coupled to a retractor 202 which is substantially the same as the retractor 12 of Figure 2 but may be any of the retractors described herein or any other retractor which is used to retract tissue, ribs or any other body structure. The suture organizer 200 and retractor 202 may be used for any procedure requiring access into a patient and organization of sutures and is particularly useful for valve repair and replacement procedures.

The suture organizer 200 has a flexible body 204 made of a thermoplastic tube having a wall thickness between 0.05 inch and 0.10 inch. The term "flexible" refers to any structure which can be manually deformed by the user and will generally conform to the shape of the patient. The term flexible includes inelastic, elastic and/or malleable structures. The suture organizer 200 has suture holders 206 which are adapted to retain sutures. The term "suture" as used herein refers to any surgical filament including sutures, silastics and the like. Referring to Fig. 15, the suture

holders 206 include slits 208 in the body 204 which hold the sutures. A V-shaped cut-out 210 facilitates introduction of the suture into the slit 208. The suture organizer 200 preferably includes at least ten, and more preferably at least twenty, pairs of suture holders 206.

The suture organizer 200 is preferably formed in four sections which are coupled together by at least two length-adjusting connections 212. The suture organizer 200 preferably forms a closed-loop, however, the suture organizer 200 may also include two ends to form a segment. The segment may be formed in a U-shape or a V-shape if desired without departing from the scope of the invention. Referring to Fig. 16, the connection 212 includes a cap 214 attached to the body 204. A flexible connector 216 extends through a hole 218 in the cap 220. The flexible connector 216 has a enlarged end 222 which prevents withdrawal of the connector 216. The connector 216 has a diameter which is slightly larger than the hole 218 so that a modest force is required to move the connector 216 through the hole 218. A user may easily push or pull the connector 216 through the hole 218, however, the interference fit prevents inadvertent slipping between the connector 216 and cap 220. Although it is preferred to provide the connector 216 and cap 220, any other length-adjusting connection 212 may be used including a threaded, ratcheted or telescoping connection. The term "length-adjusting" refers to a change in overall length whether or not the suture organizer 200 is a closed-loop or has two ends. The suture organizer 200, whether a closed-loop or a segment, preferably has a maximum length of at least 29 inches, and more preferably at least 38 inches, and has a minimum length of no more than 16 inches, and more preferably no more than 13 inches.

Referring again to Fig. 14, the suture organizer 200 is preferably attached to tabs 224 of the retractor 202. The tabs 224 are preferably the flexible straps described above in connection with Fig. 2. The tabs 224 each include a holder 226 having a number of recesses 228 sized to receive the body 204 so that the surgeon may select the desired position and

overall size of the suture organizer 200. The recesses 228 are smaller than the body 204 so that the body 204 snaps into the recess 228 but may be removed if the user desires to reposition the suture organizer 200. Alternatively, the holder 226 may be movable along the tab 224 so that the position of the holder 226 may be adjusted. For example, the holder 226 could be mounted on rails or could be releasably attached to the tab 224 with a fastener. Although it is preferred to use the holder 226, any other attachment device may be used including towel clips, a ball and socket connection, or an adhesive.

The suture organizer 200 is particularly useful in performing minimally invasive valve repair or replacement procedures. Unlike the large opening created in open-chest surgeries, the openings in the patient's chest in minimally invasive procedures are smaller and do not require conventional large rib or sternal retractors. Furthermore, the incision is generally located lateral relative to the conventional median sternotomy and, therefore, is located on a more curved surface of the body 204. An advantage of the flexible suture organizer 200 of the present invention is that it may be conformed to the curved portions of a patient's body so that the suture organizer 200 does not interfere with the procedure.

Referring to Fig. 17, another suture organizer 200A and retractor 202A are shown. The retractor 202A is substantially the same as the retractor 12 of Fig. 2, however, any of the retractors described herein or any other tissue and/or rib retractor may be used. The suture organizer 200 has a number of sections 230 having manually separable connections 232. The sections 230 may be coupled or decoupled to form the desired size of the suture organizer 200A.

The suture organizer 200A has a flexible member 234 made of plastic and having a diameter of 0.1 to 0.4 inch. A compression spring 236 extends around the flexible member 234 and is used for retaining the sutures. The sutures are simply positioned between adjacent portions of the compression spring 236 and are retained therein by the compression force of the

spring 236. Any compression spring 236 may be used and a preferred compression spring 236 has a 7/16 inch outer diameter, a wire diameter of 0.41 inch and a spring modulus K of 57 lb/in. Although it is preferred to use the compression spring 236 to hold the sutures, any other suture holder may be used including the tube of Fig. 15.

Referring to Fig. 18, the sections 230 are coupled together by a relatable connection 238 so that the surgeon may select the appropriate number or sections for the opening size and geometry. The relatable connection 238 is preferably a ball 240 and socket 242 connections although any other relatable connection may be used. As shown in Fig. 18, one section 230 is coupled to one of the tabs 224A and two other sections 230, which are coupled together by the manually relatable connection 238, are coupled to another tab 224A.

The tabs 224A of the retractor 202A include a velcro-type fastener 244 which is used to secure the suture organizer 200 to the retractor 202A. The velcro-type fastener 244 has a first strip 246 attached to the tab 224A and a second strip 248 which the user can peel away from the first strip 246 for securing the suture organizer 200 therebetween. Any other fastener may be used including the holder of Fig. 14.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity and understanding, certain changes and modifications will be obvious to those with skill in the art. For example, an adhesive tape may be used to attach the suture organizer to the retractor and both the outer ring and the anchoring structures may take a variety of forms, including articulated linkages, expandable balloons, multiple layer coils, and the like. The suture organizer may take any shape so long as the suture organizer is flexible and the suture organizer may be coupled to any retractor. Thus, the scope of the present invention is limited solely by the following claims.

WHAT IS CLAIMED IS:

1           1. A retractor for providing surgical access into  
2 a body cavity through a passage in tissue, said retractor  
3 comprising:

4           an anchoring frame having an upper surface, a lower  
5 surface, and an opening therethrough which defines an axial  
6 axis, the anchoring frame being positionable through the  
7 passage into the body cavity; and

8           a flexible tensioning member attached to the  
9 anchoring frame and extendable from the anchoring frame out of  
10 the body cavity through the passage when the anchoring frame  
11 is in the body cavity, said tensioning member being  
12 selectively tensionable to spread the tissue radially  
13 outwardly from the axial axis.

1           2. A retractor as claimed in claim 1, wherein the  
2 anchoring frame is ring-shaped.

1           3. A retractor as claimed in claim 1, wherein the  
2 flexible tensioning member is configured to compress the  
3 tissue adjacent the passage against the upper surface of the  
4 anchoring frame.

1           4. A retractor as claimed in claim 1, wherein the  
2 anchoring frame has a narrow profile configuration for  
3 insertion through the passage and is deployable into a wide  
4 profile configuration while inside the body cavity, the  
5 anchoring frame having a width across the upper surface in the  
6 wide profile configuration which is wider than the passage.

1           5. A retractor as claimed in claim 4, wherein the  
2 anchoring frame comprises a resilient material which may be  
3 collapsed into the narrow profile configuration and which  
4 expands to the wide profile configuration when released in the  
5 body cavity.

1           6. A retractor as claimed in claim 4, wherein the  
2 frame comprises a deployment mechanism for mechanically  
3 expanding the frame from the narrow profile configuration to  
4 the wide profile configuration.

1           7. A retractor as claimed in claim 1, wherein the  
2 tensioning member comprises a plurality of flexible tabs which  
3 are axially extendable from the frame on opposing sides of the  
4 opening.

1           8. A retractor as claimed in claim 7, wherein the  
2 tabs comprise adhesive strips.

1           9. A retractor as claimed in claim 1, wherein the  
2 tensioning member comprises an elastic or semi-elastic sheet  
3 of material, and wherein the sheet is tensionable in a  
4 plurality of outward radial directions relative to the frame.

1           10. A retractor as claimed in claim 1, further  
2 comprising an attachment mechanism on an extremity of the  
3 tensioning member spaced apart from the frame for attachment  
4 outside of the body cavity to hold the tissue in a retracted  
5 position.

1           11. A retractor as claimed in claim 1, further  
2 comprising an adhesive disposed on the tensioning member for  
3 attachment outside of the body cavity to hold the tissue in a  
4 retracted position.

1           12. A retractor as claimed in claim 1, further  
2 comprising an outer frame structure attached to the tensioning  
3 member and axially separated from the anchoring frame for  
4 positioning outside the body cavity, the outer frame structure  
5 having an outer opening aligned with the opening of the  
6 anchoring frame to provide access therethrough.

1           13. A retractor as claimed in claim 12, wherein the  
2 outer frame structure includes a plurality of suture retainers  
3 disposed about the outer frame opening.

1           14. A retractor as claimed in claim 1, further  
2 comprising an illuminating device disposed adjacent to the  
3 opening of the frame for conducting light into the body  
4 cavity.

1           15. A retractor as claimed in claim 1, wherein the  
2 frame has a narrow profile configuration for insertion through  
3 the passage and is expandable to a wide profile configuration  
4 within the chest cavity, the anchoring frame in the narrow  
5 configuration having a width smaller than an intercostal  
6 width.

1           16. A retractor as claimed in claim 15, wherein the  
2 anchoring frame in the wide profile configuration has a  
3 dimension across the opening larger than the intercostal  
4 width.

1           17. A retractor as claimed in claim 15, wherein the  
2 anchoring frame comprises a resilient material which may be  
3 collapsed into the narrow profile configuration and which  
4 expands to the wide profile configuration when released in the  
5 body cavity.

1           18. A retractor as claimed in claim 17, wherein the  
2 anchoring frame comprises a superelastic material.

1           19. A retractor for providing surgical access into  
2 a chest cavity defined by a plurality of ribs, the ribs being  
3 separated by intercostal tissue and an intercostal width, the  
4 retractor comprising:  
5           an anchoring frame having an upper surface, a lower  
6 surface, and an opening therethrough, the frame being  
7 insertable into the chest cavity through a passage between two  
8 ribs; and



9           a flexible tensioning member attached to the frame  
10   on at least two opposing sides of the opening, the tensioning  
11   member extendable out of the chest cavity through the passage  
12   when the frame is within the chest cavity and the opening is  
13   generally aligned with the passage, said tensioning member  
14   selectively tensionable to spread the intercostal tissue along  
15   the passage outward toward the two ribs.

1           20. A retractor as claimed in claim 19, further  
2   comprising an attachment mechanism on an extremity of the  
3   tensioning member spaced apart from the anchoring frame for  
4   attachment outside the chest cavity to hold the intercostal  
5   tissue in a retracted position.

1           21. A retractor as claimed in claim 19, wherein the  
2   tensioning member is configured to exert tension outwardly  
3   from the frame in a plurality of radially opposed directions.

1           22. A retractor as claimed in claim 19, wherein the  
2   anchoring frame is ring-shaped.

1           23. A retractor as claimed in claim 19, wherein the  
2   opening has a radial dimension of between about 10 mm and  
3   9 cm.

1           24. A retractor as claimed in claim 15, wherein the  
2   tensioning member comprises a plurality of flexible tabs.

1           25. A retractor as claimed in claim 24, wherein the  
2   tabs comprise an elastomeric material.

1           26. A retractor as claimed in claim 24, wherein the  
2   tabs comprise an absorbent material.

1           27. A retractor as claimed in claim 16, wherein the  
2   attachment mechanism comprises adhesive.

1           28. A retractor as claimed in claim 16, further  
2 comprising an outer frame structure attached to the tensioning  
3 member and axially separated from the anchoring frame for  
4 positioning outside the body cavity, the outer frame structure  
5 having an outer opening aligned with the opening of the  
6 anchoring frame to provide access therethrough.

1           29. A retractor as in claim 28 wherein the  
2 attachment mechanism comprises a plurality of clasps for  
3 attaching the tensioning member to the outer frame structure.

1           30. A retractor as claimed in claim 15, further  
2 comprising an illuminating device disposed adjacent to the  
3 opening of the frame for conducting light into the body  
4 cavity.

1           31. An illuminating retractor for providing  
2 surgical access to a body cavity of a patient through a  
3 passage in tissue, the retractor comprising:  
4           an internal anchor having an opening, the internal  
5 anchor being insertable through the passage and into the body  
6 cavity;  
7           a tissue restraining structure extending proximally  
8 from the internal anchor for holding the passage open  
9 sufficiently to provide direct visualization of the internal  
10 body cavity from outside the patient;  
11          an external anchor on the tissue restraining  
12 structure spaced proximally from the internal anchor; and  
13          an illuminating device disposed adjacent the opening  
14 in the internal anchor to facilitate visualization through the  
15 open passage.

1           32. An illuminated retractor as claimed in claim  
2 31, wherein the illuminating device comprises a plurality of  
3 optical fibers having distal ends oriented toward the body  
4 cavity.

1           33. An illuminated retractor as claimed in claim  
2 32, wherein the plurality of optical fibers are independent of  
3 the tissue restraining structure.

1           34. An illuminated retractor as claimed in claim  
2 32, wherein the plurality of optical fibers are mounted to the  
3 tissue restraining structure.

1           35. An illuminated retractor as claimed in claim  
2 31, wherein the internal anchor comprises an anchoring frame  
3 having an opening, the tissue restraining structure comprises  
4 a liner extending from the frame at least partially around the  
5 opening, and the external anchor is configured to maintain  
6 outward radial tension in the liner.

1           36. An illuminating retractor for providing  
2 surgical access to a body cavity of a patient through a  
3 passage in tissue, the retractor comprising:

4           an internal anchor having an opening, the internal  
5 anchor being insertable through the passage and into the body  
6 cavity;

7           a flexible tissue restraining structure extending  
8 proximally from the internal anchor, the tissue restraining  
9 structure configured to be secured in tension outside the body  
10 cavity so as to hold the passage open sufficiently to provide  
11 direct visualization of the internal body cavity from outside  
12 the patient; and

13           an illuminating device disposed adjacent the opening  
14 in the internal anchor to facilitate visualization through the  
15 open passage.

1           37. A tissue retractor system for providing  
2 surgical access through an incision in tissue to a body cavity  
3 of a patient, the system comprising:

4           a retractor comprising:

5           an anchoring frame having an opening, the frame  
6 being restrainable into a narrow profile to facilitate  
7 insertion through the incision into the body cavity and being

8 expandable to a wide profile when inside the body cavity, the  
9 wide profile being wider than the narrow profile;  
10 a flexible tensioning member extending from the  
11 frame adjacent to the opening, said tensioning member being  
12 selectively tensionable to spread the tissue adjacent to the  
13 incision and being adapted to be secured in tension outside  
14 the body cavity; and  
15 a retractor delivery device comprising:  
16 a device body having a distal end and a  
17 proximal end;  
18 a pair of inward facing surfaces near the  
19 distal end capable of releasably restraining the frame  
20 therebetween in the narrow profile; and  
21 a handle at the proximal end for supporting the  
22 inward facing surfaces.

38. A tissue retractor system as claimed in claim  
37 wherein the frame is resiliently expandable into the wide  
profile configuration.

1 39. A tissue retractor system as claimed in claim  
2 38, wherein the handle includes an actuator for releasing the  
3 frame to expand into the wide profile within the body cavity.

1 40. A tissue retractor system as claimed in  
2 claim 39, wherein actuation of the actuator enlarges a gap  
3 between the inward facing surfaces.

1 41. A tissue retractor system as claimed in  
2 claim 40, wherein the inward facing surfaces are disposed on a  
3 pair of generally U-shaped arms at the distal end of the  
4 device body.

1 42. A tissue retractor system as claimed in  
2 claim 37, further comprising an outer frame structure to which  
3 the tensioning member may be attached to maintain the  
4 tensioning member in tension.

1           43. A tissue retractor system as claimed in  
2 claim 41, wherein the outer frame structure is expandable to  
3 apply tension to the tensioning member.

1           44. A tissue retractor system as claimed in  
2 claim 41, further comprising a plurality of clasps for  
3 attaching the tensioning member to the outer frame structure.

1           45. A tissue retractor system as claimed in  
2 claim 38, wherein actuation of the handle slides the frame  
3 distally relative to the inward facing surfaces.

1           46. A tissue retractor system as claimed in  
2 claim 38, wherein a tether extends from the tensioning member  
3 to the delivery device.

1           47. A tissue retractor delivery device for use with  
2 a retractor comprising an anchoring frame restrainable into a  
3 narrow profile for insertion through an incision into a body  
4 cavity, the frame expandable to a wide profile wider than the  
5 incision and having an opening, a tensioning member extending  
6 from the frame adjacent to the opening, the tensioning member  
7 being selectively tensionable to spread tissue outward from  
8 the incision so as to provide surgical access into the body  
9 cavity, the delivery device comprising:  
10           a device body having distal and proximal ends;  
11           a pair of inward facing surfaces near the distal end  
12 which restrain the frame to the small profile;  
13           a handle near the proximal end for supporting the  
14 inward facing surfaces; and  
15           an actuator on the handle for effecting expansion of  
16 the frame to the wide profile within the body cavity.

1           48. A delivery device as claimed in claim 46,  
2 wherein actuation of the actuator increases a gap between the  
3 inward facing surfaces.

1           49. A tissue retractor system as claimed in  
2 claim 47, wherein the inward-facing surfaces are disposed on a  
3 pair of generally U-shaped arms extending from the proximal  
4 end of the device body.

1           50. A method for retracting tissue to temporarily  
2 widen a penetration into a body cavity, the method comprising:  
3           positioning an anchoring frame against a tissue  
4 surface within the body cavity adjacent to the penetration so  
5 that an opening in the frame is aligned with the penetration,  
6 the frame having a width across the opening wider than the  
7 penetration; and  
8           tensioning a flexible tissue restraining member  
9 extending from the frame and out of the body cavity through  
10 the penetration so as to urge the tissue adjacent to the  
11 penetration outwardly.

1           51. A method as claimed in claim 50, wherein the  
2 tensioning step comprises applying tension in an outward  
3 radial direction from the frame.

1           52. A method as claimed in claim 50, wherein the  
2 tensioning step comprises applying the tension in a plurality  
3 of radially opposed directions.

1           53. A method as claimed in claim 50, further  
2 comprising surgically accessing a body cavity through the  
3 penetration and the opening in the frame while maintaining the  
4 tension.

1           54. A method as claimed in claim 53, wherein the  
2 surgically accessing step comprises directly observing tissues  
3 within the body cavity through the opening in the frame.

1           55. A method as claimed in claim 53, wherein the  
2 surgically accessing step comprises optically observing  
3 tissues within the body cavity through the opening in the  
4 frame from outside the body using magnification optics.

1           56. A method as claimed in claim 51, further  
2 comprising expanding the frame from a narrow profile to a  
3 large profile while inside the body cavity, wherein the frame  
4 retains the large profile while the tissue restraining member  
5 is tensioned.

1           57. A method as claimed in claim 56, wherein the  
2 expanding step comprises releasing the frame and allowing it  
3 to expand resiliently.

1           58. A method as claimed in claim 56, further  
2 comprising inserting the frame through the passage into the  
3 body cavity in the narrow profile.

1           59. A method as claimed in claim 58, wherein the  
2 inserting step comprises introducing the frame angled edgewise  
3 through the passage.

1           60. A method as claimed in claim 50 further  
2 comprising securing the tissue restraining member outside the  
3 body cavity.

1           61. A method as claimed in claim 60, wherein the  
2 securing step comprises adhesively attaching the tissue  
3 restraining member to an external surface of the patient's  
4 body.

1           62. A method for performing surgery on a patient's  
2 heart, the heart being disposed within a chest cavity defined  
3 by a plurality of ribs, the ribs being separated by  
4 intercostal tissue and an intercostal width, the method  
5 comprising:

6           inserting an anchoring frame into the chest cavity  
7 through an incision between two ribs, the frame having an  
8 opening and a width across the opening wider than the  
9 intercostal width;

10           applying tension to at least one flexible tab  
11       extending out of the chest cavity from the frame adjacent to  
12       the opening so as to widen the incision; and  
13           performing surgery on the heart using instruments  
14       positioned through the widened incision.

1           63. A method of organizing sutures during a  
2       surgical procedure, comprising:  
3           providing a flexible suture organizer having a  
4       plurality of suture holders;  
5           deforming the flexible suture organizer so that the  
6       flexible suture organizer generally conforms to the patient's  
7       body; and  
1           fixing a plurality of sutures in the suture holders.

1           64. The method of claim 63, wherein:  
2           the providing step is carried out with the flexible  
3       suture organizer having an adjustable length.

1           65. The method of claim 63, further comprising the  
2       steps of:  
3           coupling the suture organizer to a retractor; and  
4           retracting a body structure with the retractor, the  
5       retractor forming an opening through which the plurality of  
6       sutures extend.

1           66. The method of claim 65, wherein:  
2           the retracting step is carried out with the  
3       retractor having at least one flexible tab which extends  
4       through the opening, the retracting step being carried out by  
5       tensioning the flexible tab.

1           67. The method of claim 63, wherein:  
2           the providing step is carried out with the suture  
3       organizer being a flexible tube and the suture holders being  
4       slits in the flexible tube.



1           68. A suture organizer comprising: a plurality of  
2 suture holders each being configured to retain a suture  
3 therein, the suture holders being positioned on a flexible  
4 body, the flexible body being configured so that a surgeon may  
5 deform the flexible body to generally conform to the shape of  
6 a patient.

1           69. The suture organizer of claim 68 wherein: the  
2 body includes a length adjusting mechanism for adjusting a  
3 length of the flexible body, the length adjusting mechanism  
4 being movable between a first position and a second position,  
5 the suture organizer having a larger length when in the second  
6 position.

1           70. The suture organizer of claim 69 wherein: the  
2 length adjusting mechanism is a slidable connection between a  
3 first portion and a second portion of the flexible body.

1           71. The suture organizer of claim 68, wherein: the  
2 flexible body includes a first part and a second part, the  
3 first and second parts being manually separable.

4           72. The suture organizer of claim 68, further  
5 comprising: a retractor coupled to the body, the retractor  
6 having a movable part adapted to retract a body structure in a  
7 patient.

1           73. A device for organizing sutures, comprising:  
2 a first section having a first plurality of suture  
3 holders; and  
4 a second section having a second plurality of suture  
5 holders, the first section being realizable attached to the  
6 first section.

1           74. The suture organizer of claim 73, wherein:  
2 the first section is flexible so that the first  
3 section may generally conform to the shape of a patient.

1           75. The suture organizer of claim 73, further  
2 comprising:  
3           a retractor having a movable part configured to  
4 retract a body structure and create an opening in the patient;  
5           the first and second sections being coupled to the  
6 retractor.

1           76. A device for retracting a body structure and  
2 organizing sutures, comprising:  
3           a retractor having at least one movable part for  
4 retracting a body structure; and  
5           a suture organizer coupled to the retractor, the  
6 suture organizer having a plurality of suture holders.

1           77. The device of claim 76, wherein:  
2           the movable part of the retractor is a flexible  
3 strap attached to an anchoring member, the anchoring member  
4 being movable from a first shape, for inserting the anchoring  
5 member into a patient, to a second shape, for anchoring the  
6 anchoring member within the patient.

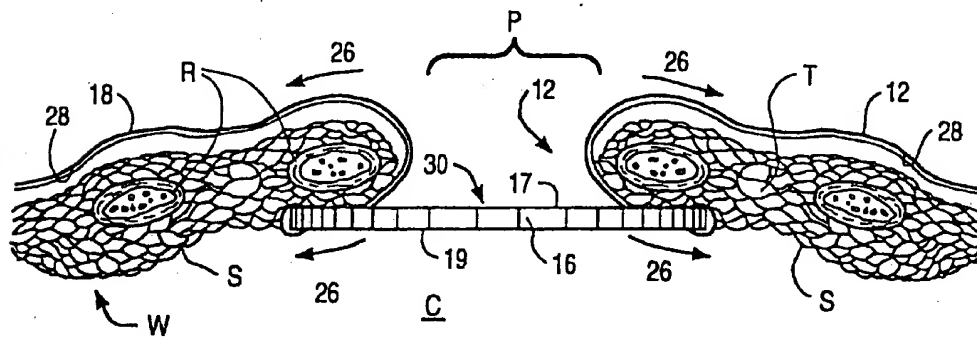
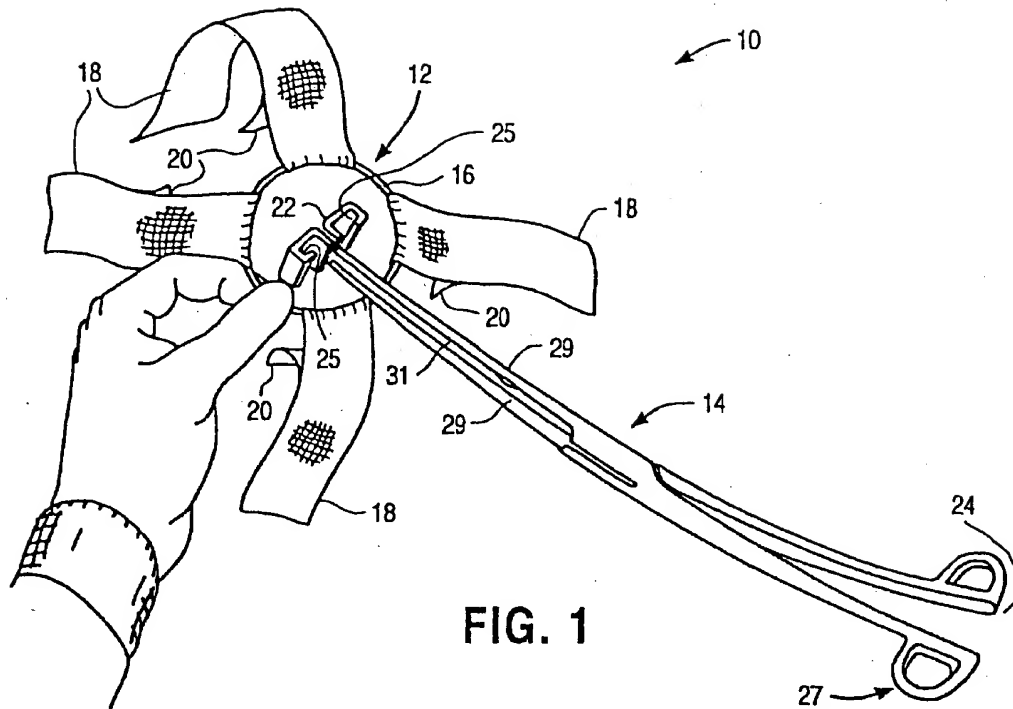
1           78. The device of claim 76, wherein:  
2           the suture organizer is flexible so that the suture  
3 organizer may generally conform to the shape of a patient.

1           79. The device of claim 76, wherein:  
2           the suture organizer includes a flexible tube, the  
3 plurality of suture holders including slits in the flexible  
4 tube.

1           80. The device of claim 76, wherein:  
2           the suture organizer includes a length adjusting  
3 mechanism for adjusting a length of the suture organizer, the  
4 length adjusting mechanism being movable from a first position  
5 to a second position, the suture organizer having a larger  
6 length when the length adjusting mechanism is in the second  
7 position than when the length adjusting mechanism is in the  
8 first position.

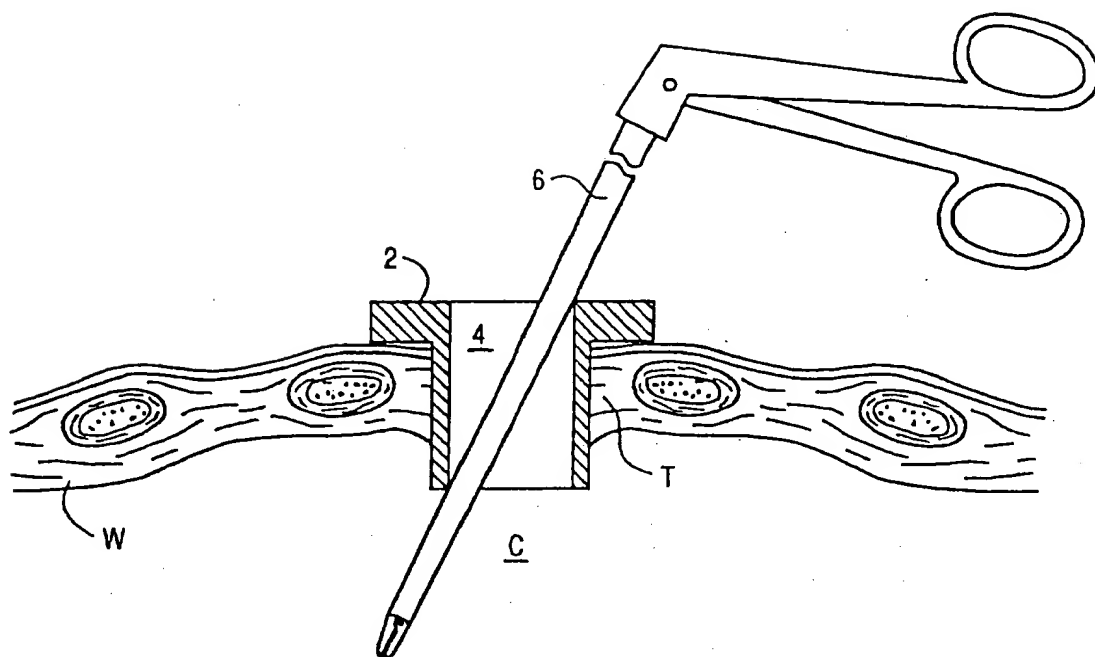
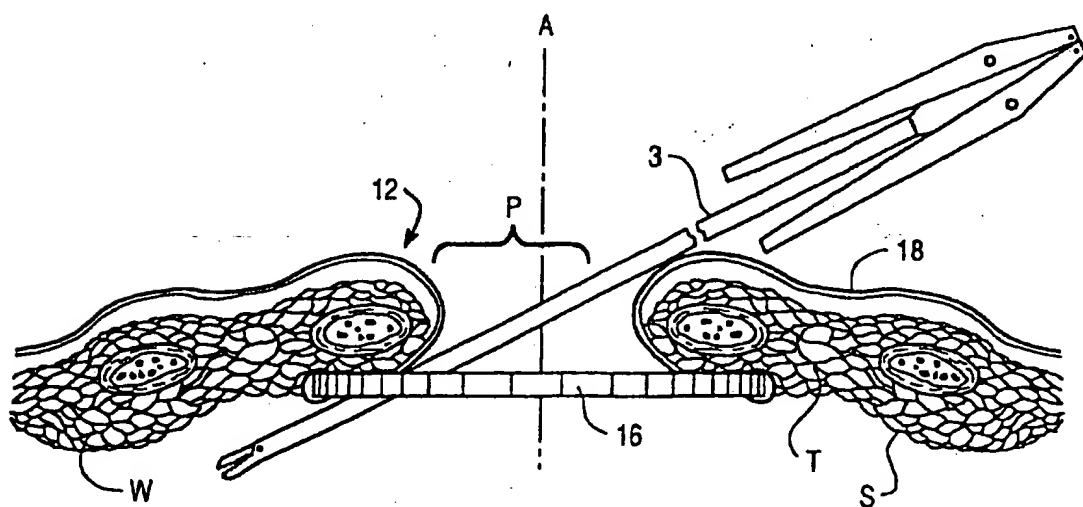
1           81. A retractor for providing surgical access into  
2 a body cavity through a passage in tissue, comprising:  
3           an anchoring frame having an upper surface, a lower  
4 surface, and an opening therethrough which defines an axial  
5 axis, the anchoring frame being positionable through the  
6 passage into the body cavity; and  
7           a flexible tensioning member attached to the  
8 anchoring frame and extendable from the anchoring frame out of  
9 the body cavity through the passage when the anchoring frame  
10 is in the body cavity, said tensioning member selectively  
11 tensionable to spread the tissue radially outwardly from the  
12 axial axis.

1 / 19



SUBSTITUTE SHEET (RULE 26)

2/19

**FIG. 2B (PRIOR ART)****FIG. 2B**

3/19

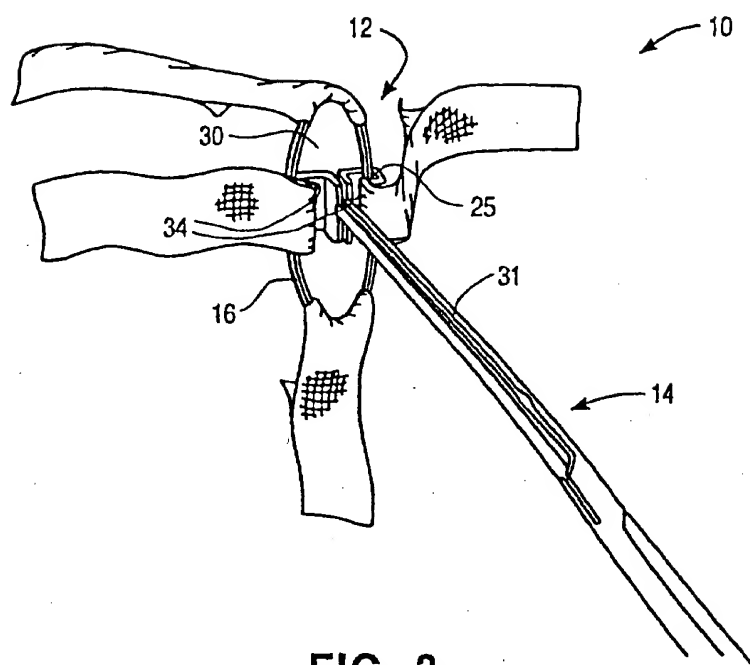


FIG. 3

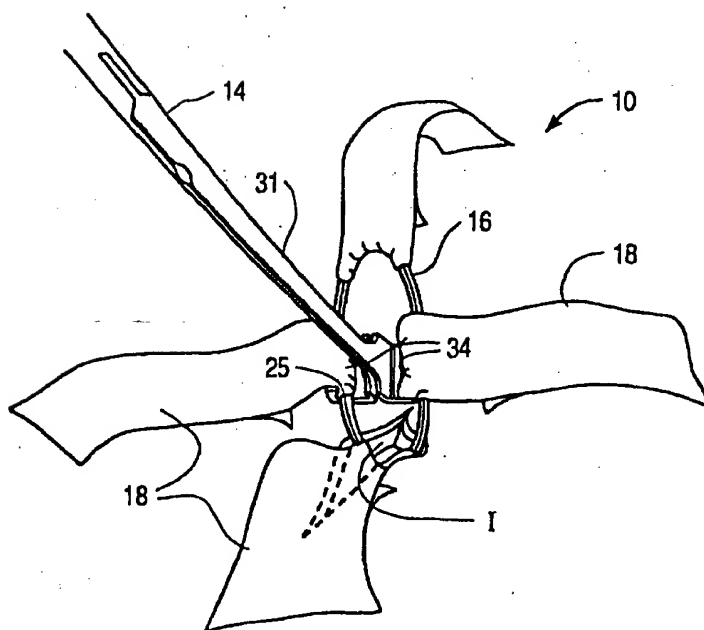


FIG. 4

4/19

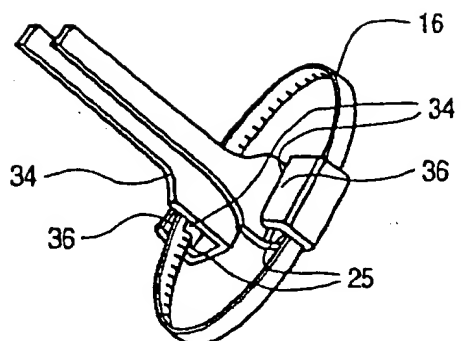


FIG. 4A

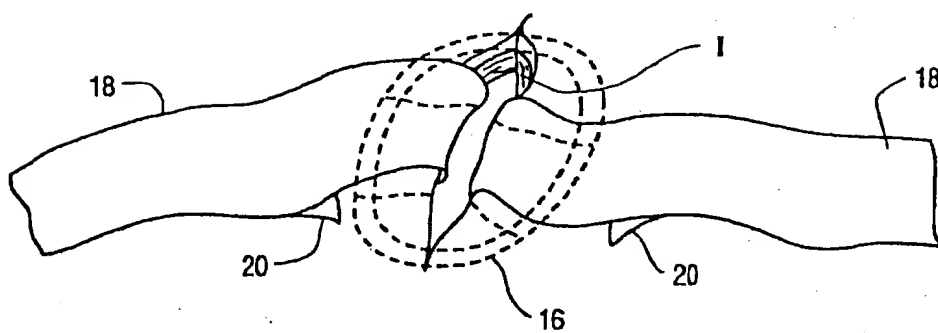


FIG. 5

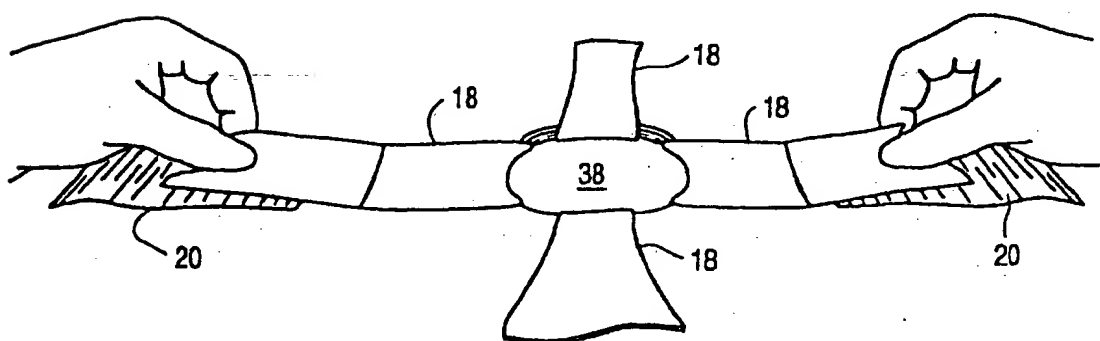


FIG. 6

5 / 19

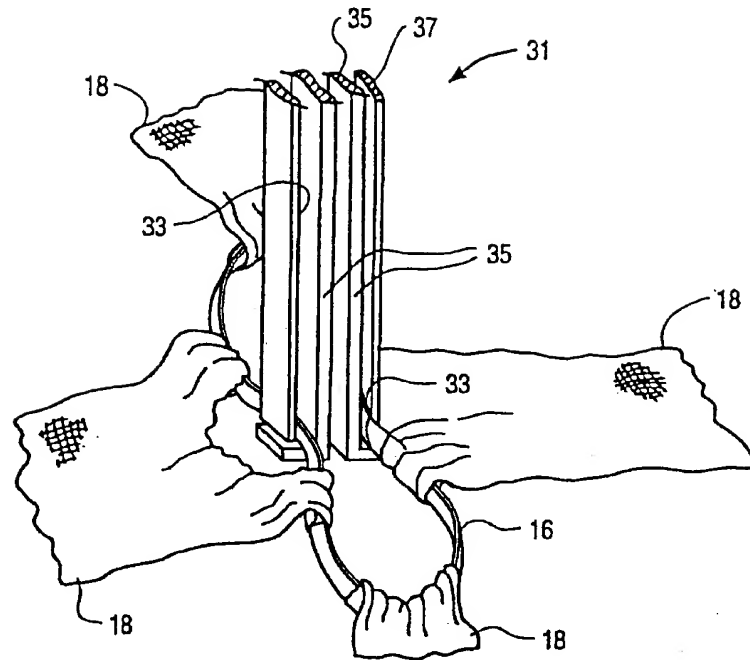


FIG. 6A

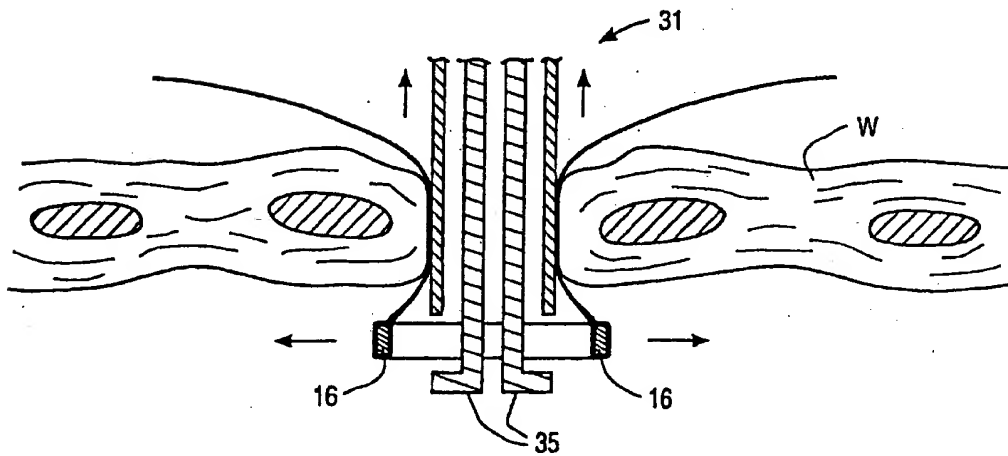


FIG. 6B



6/19

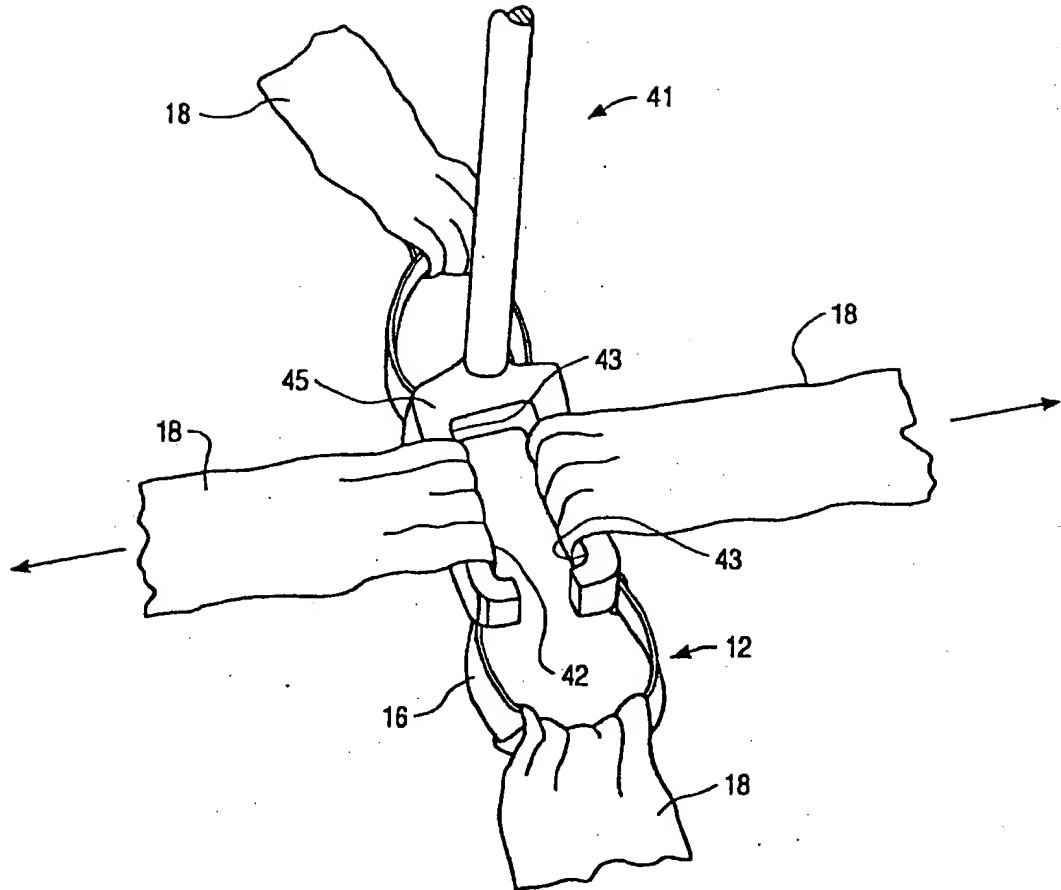


FIG. 6C

7/19

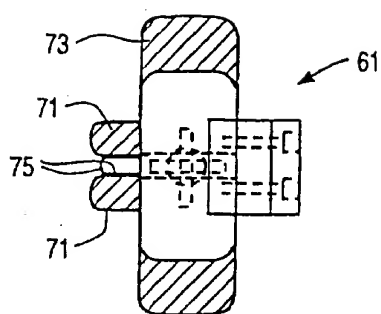


FIG. 6G

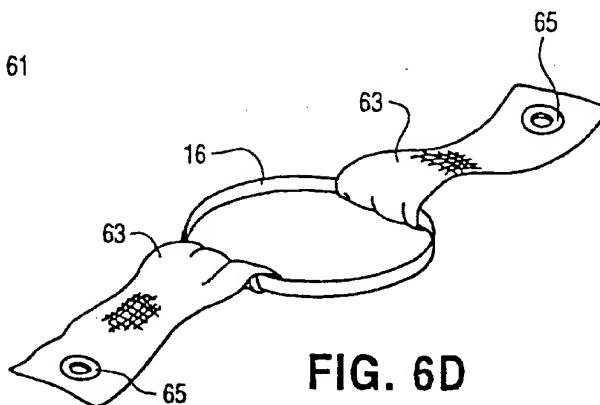


FIG. 6D

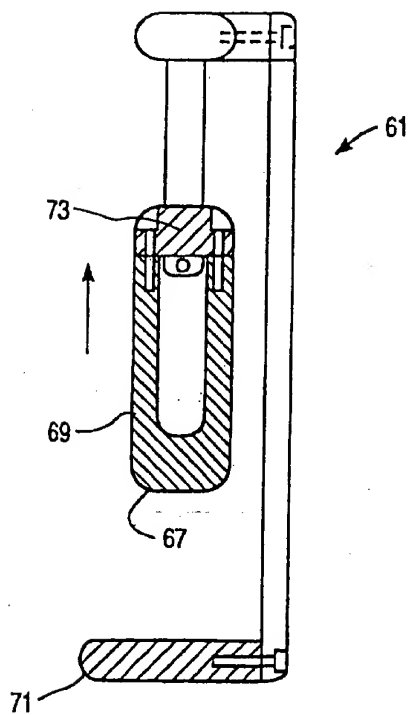


FIG. 6F

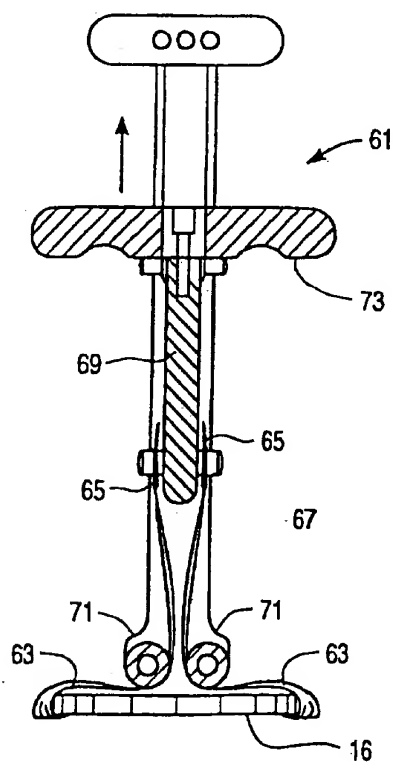


FIG. 6E

8 / 19

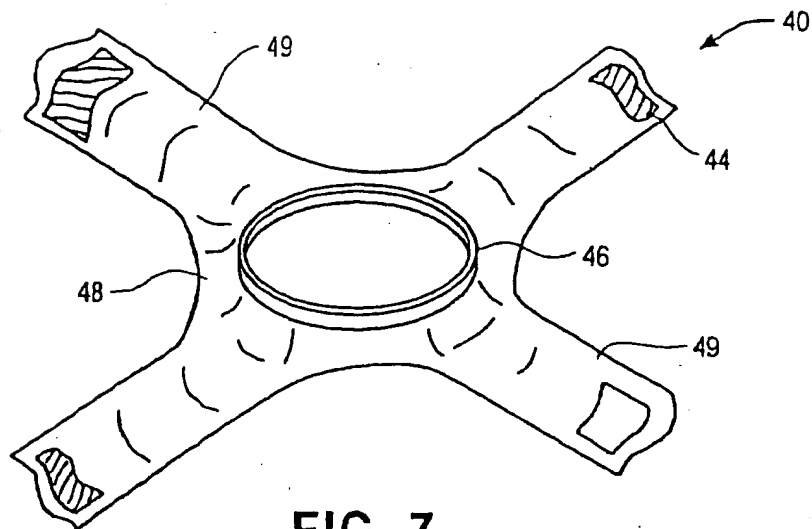


FIG. 7

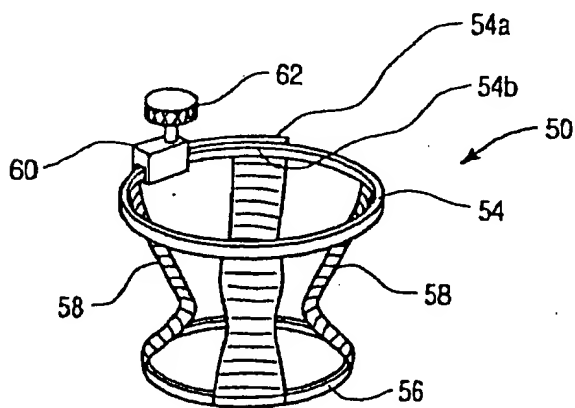


FIG. 8

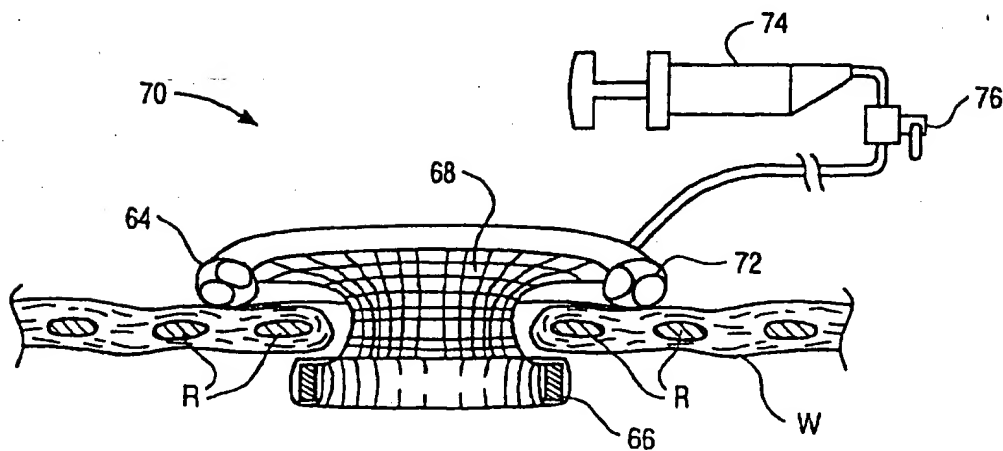


FIG. 9

9/19

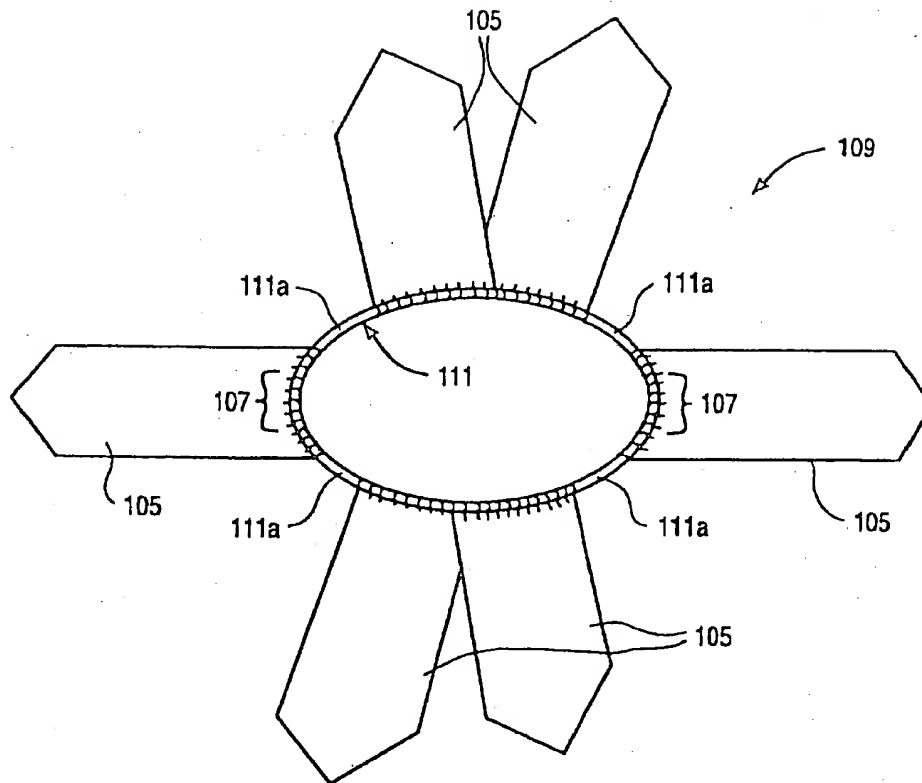


FIG. 9A

SUBSTITUTE SHEET (RULE 26)

10 / 19

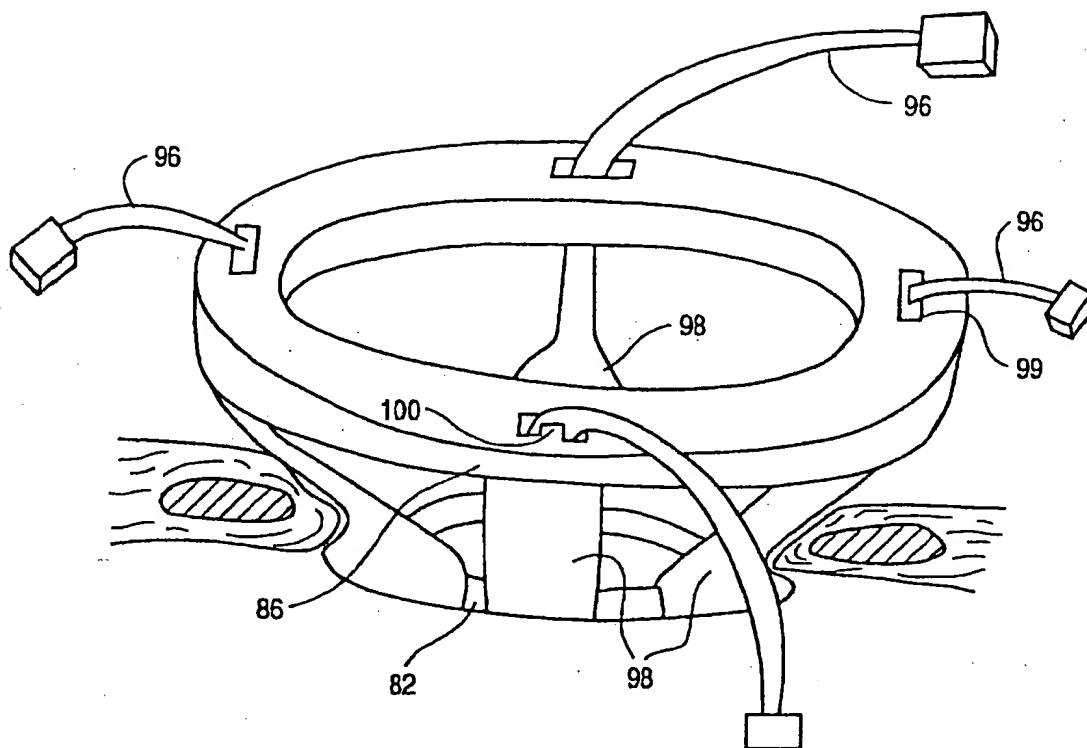


FIG. 10A

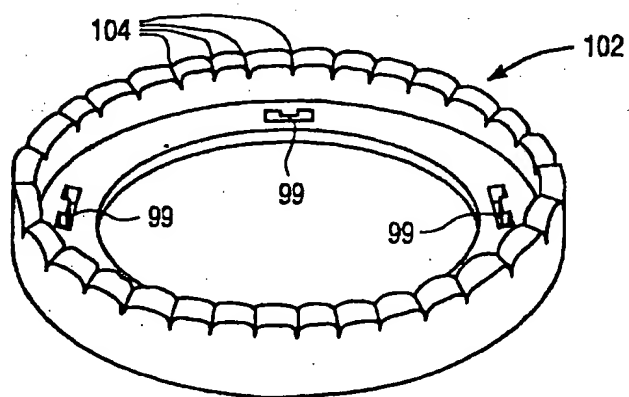
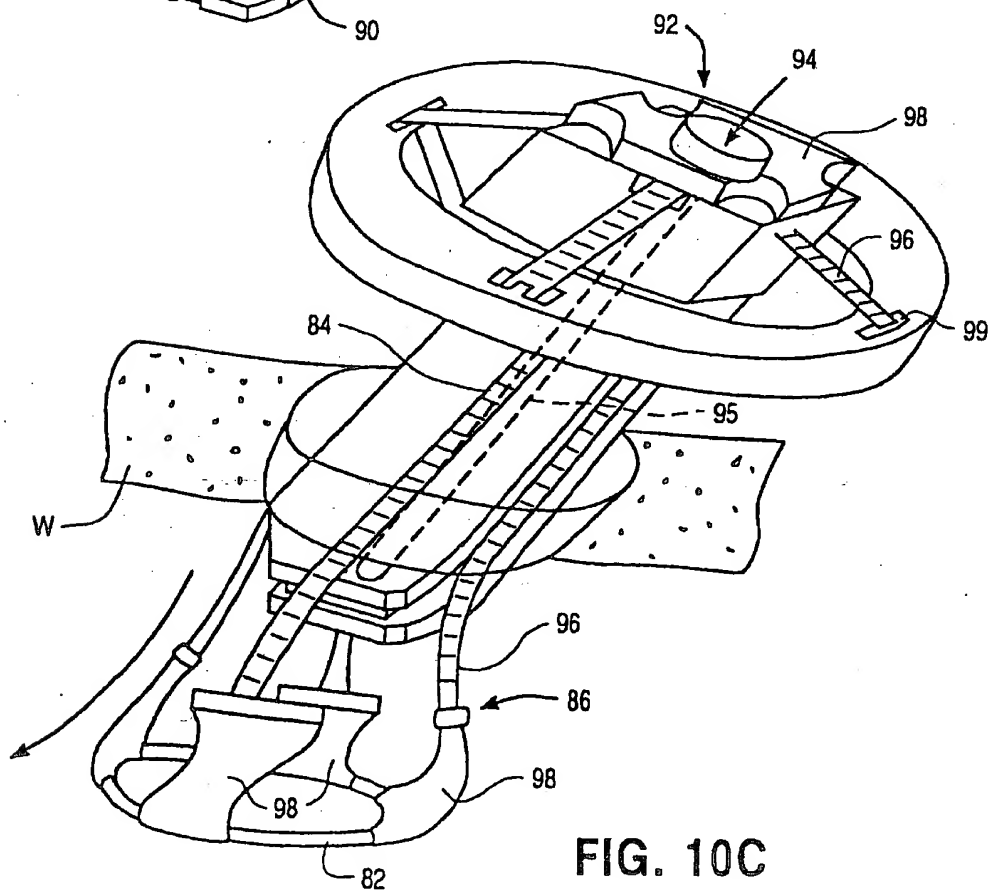
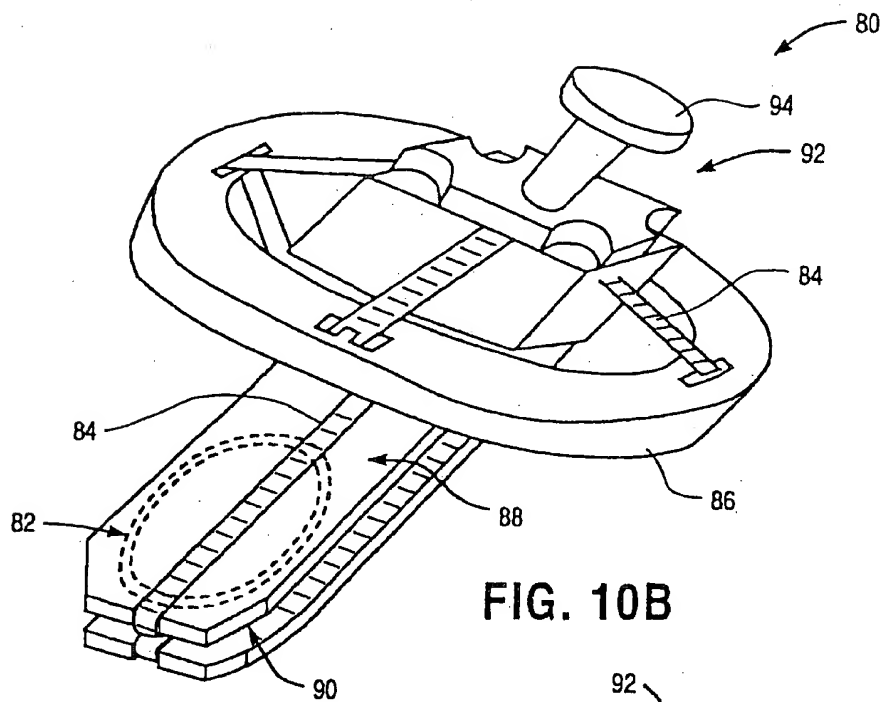


FIG. 10F

11 / 19



12 / 19

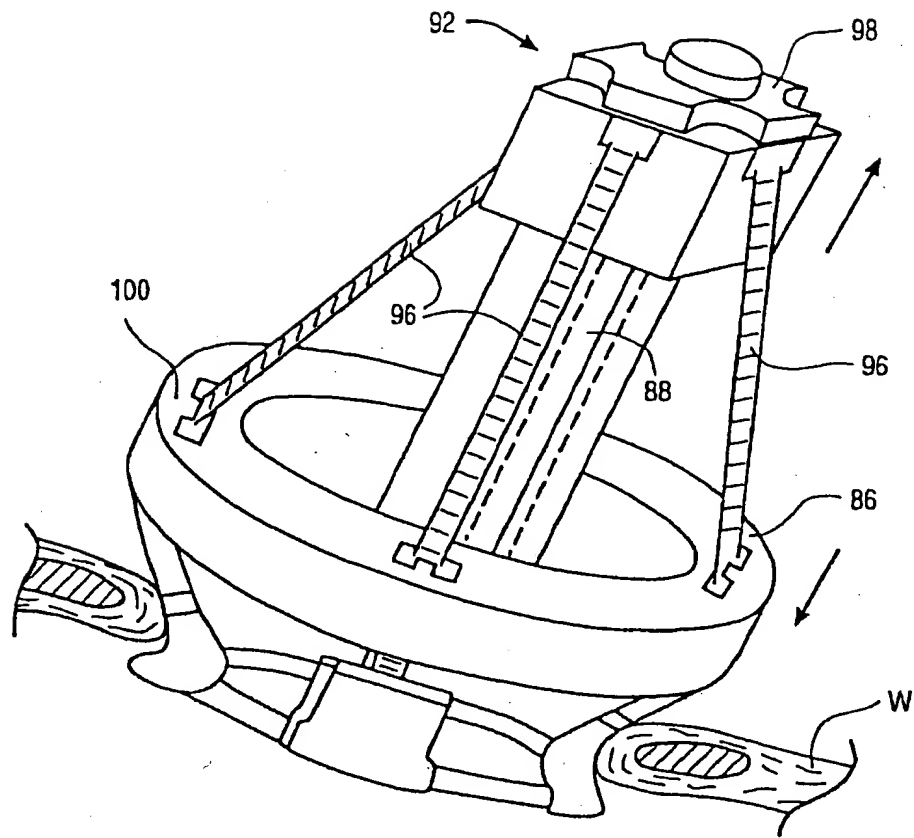


FIG. 10D

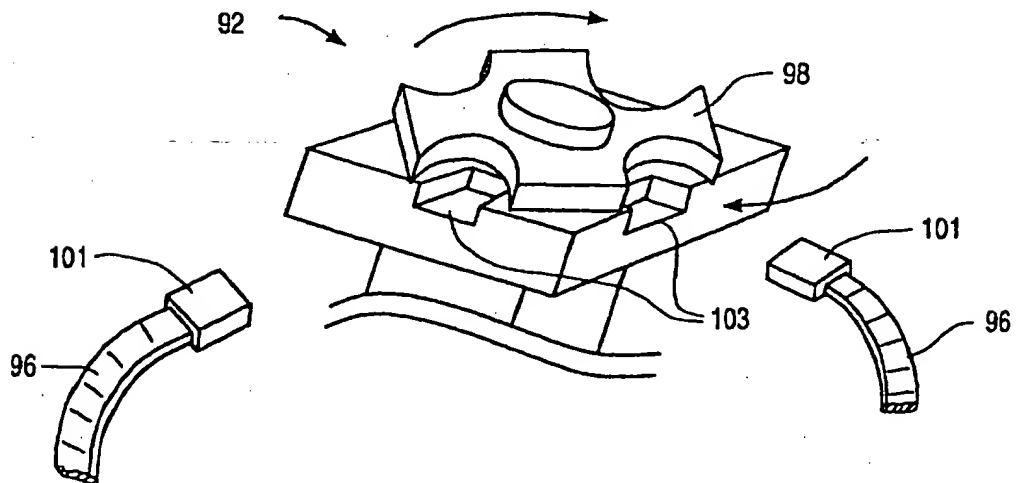
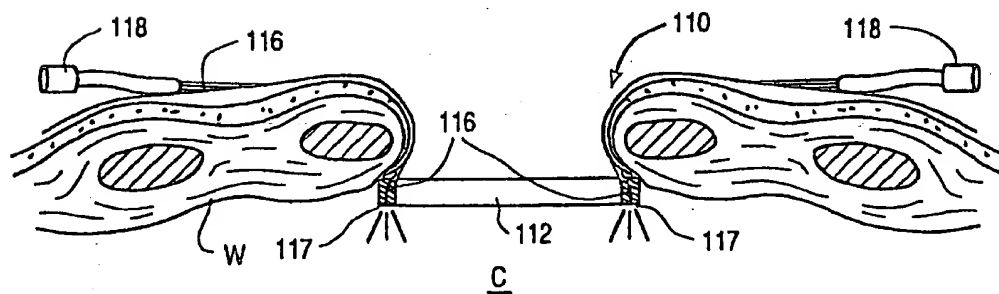
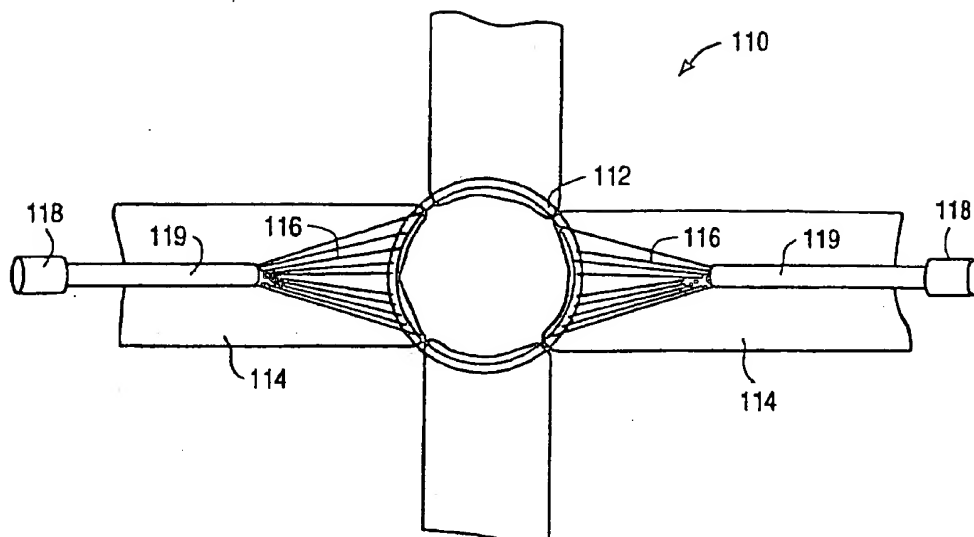


FIG. 10E

13 / 19



**SUBSTITUTE SHEET (RULE 26)**



14 / 19

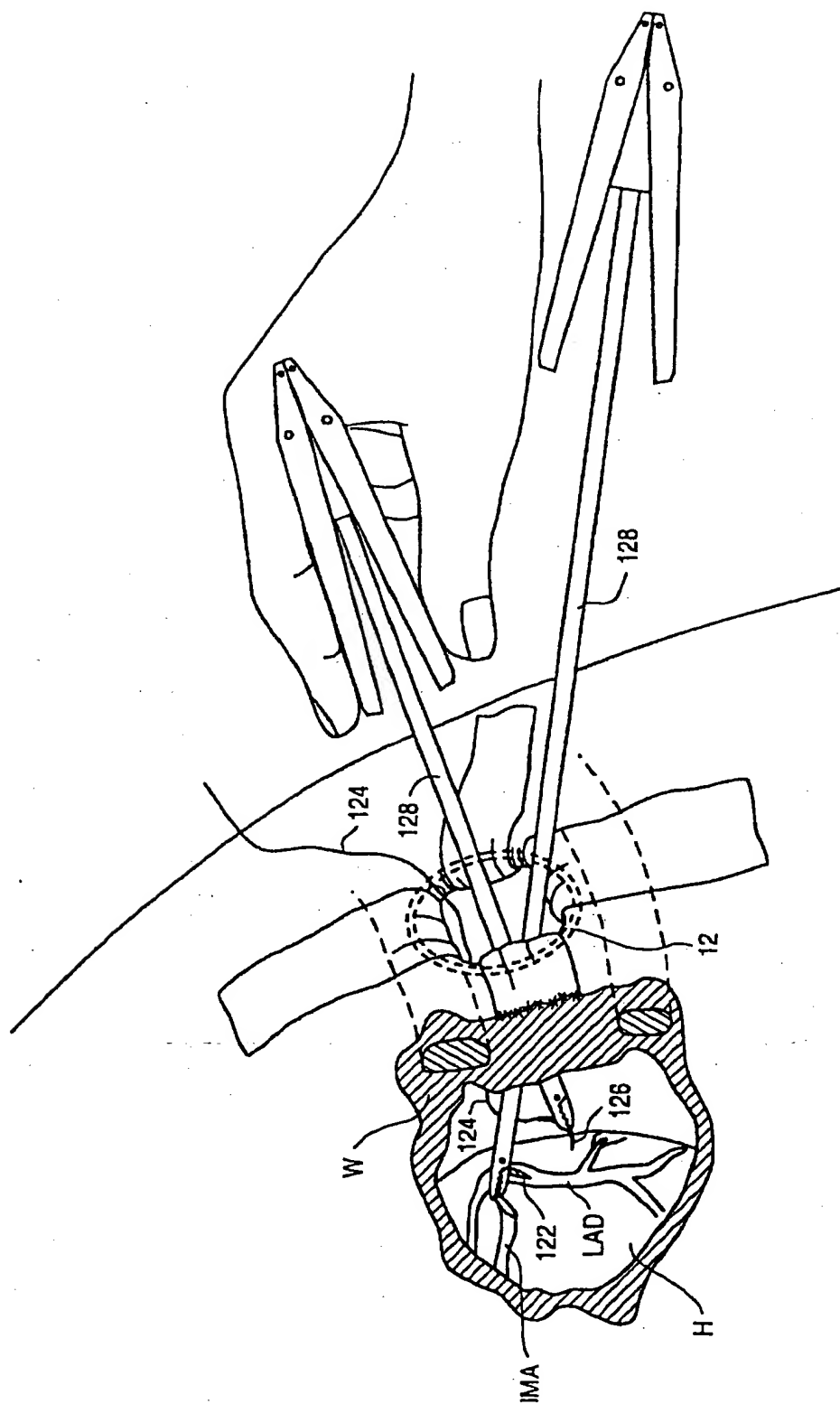


FIG. 12A

15/19

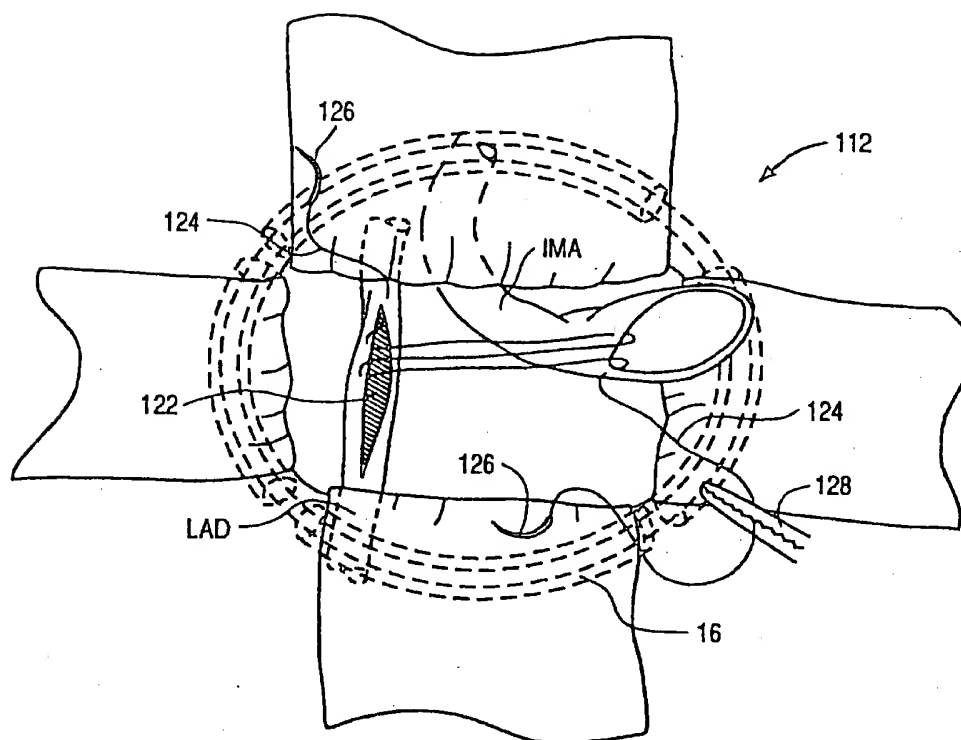


FIG. 12B

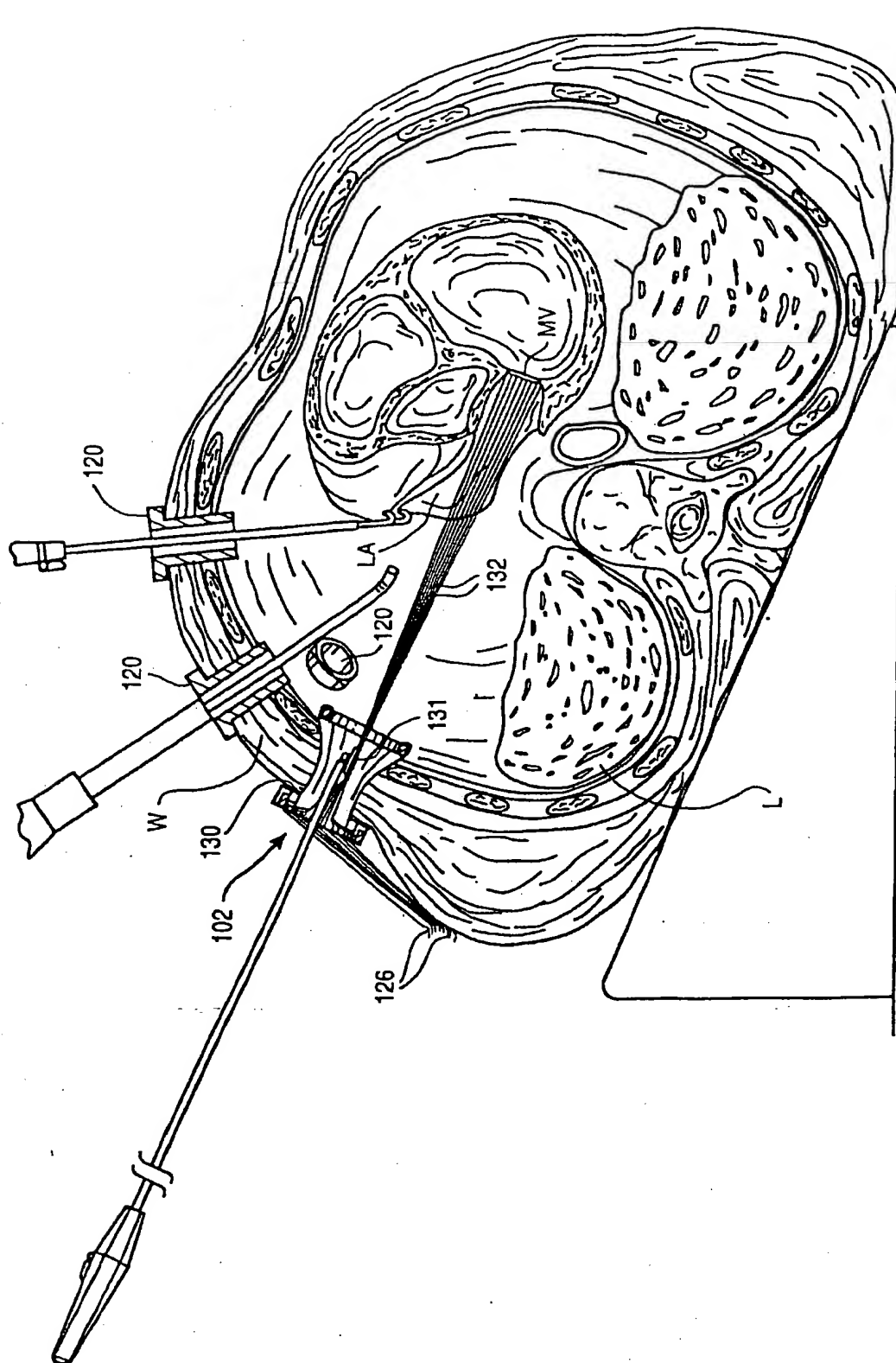
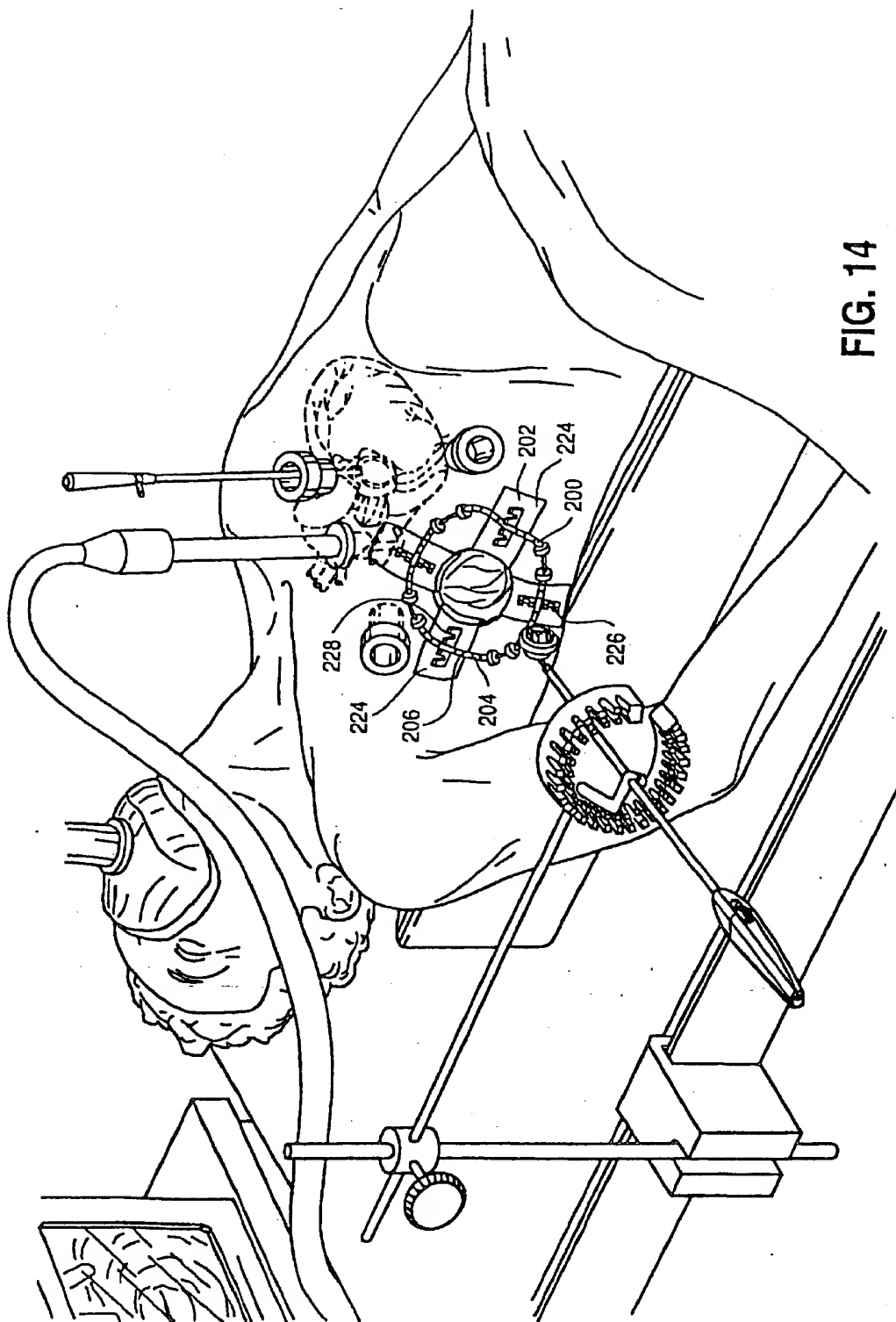


FIG. 13

17 / 19



18 / 19

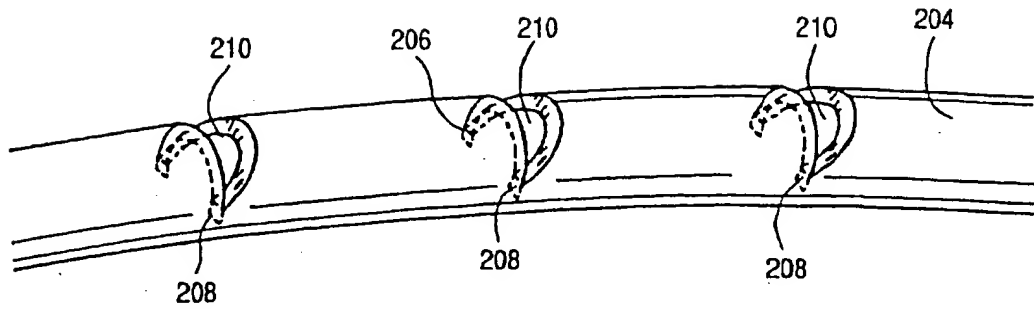


FIG. 15

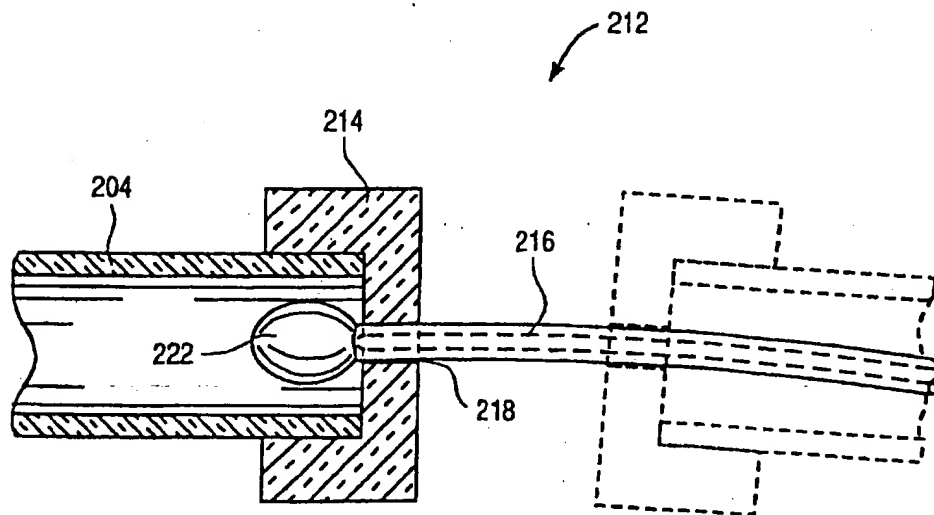


FIG. 16

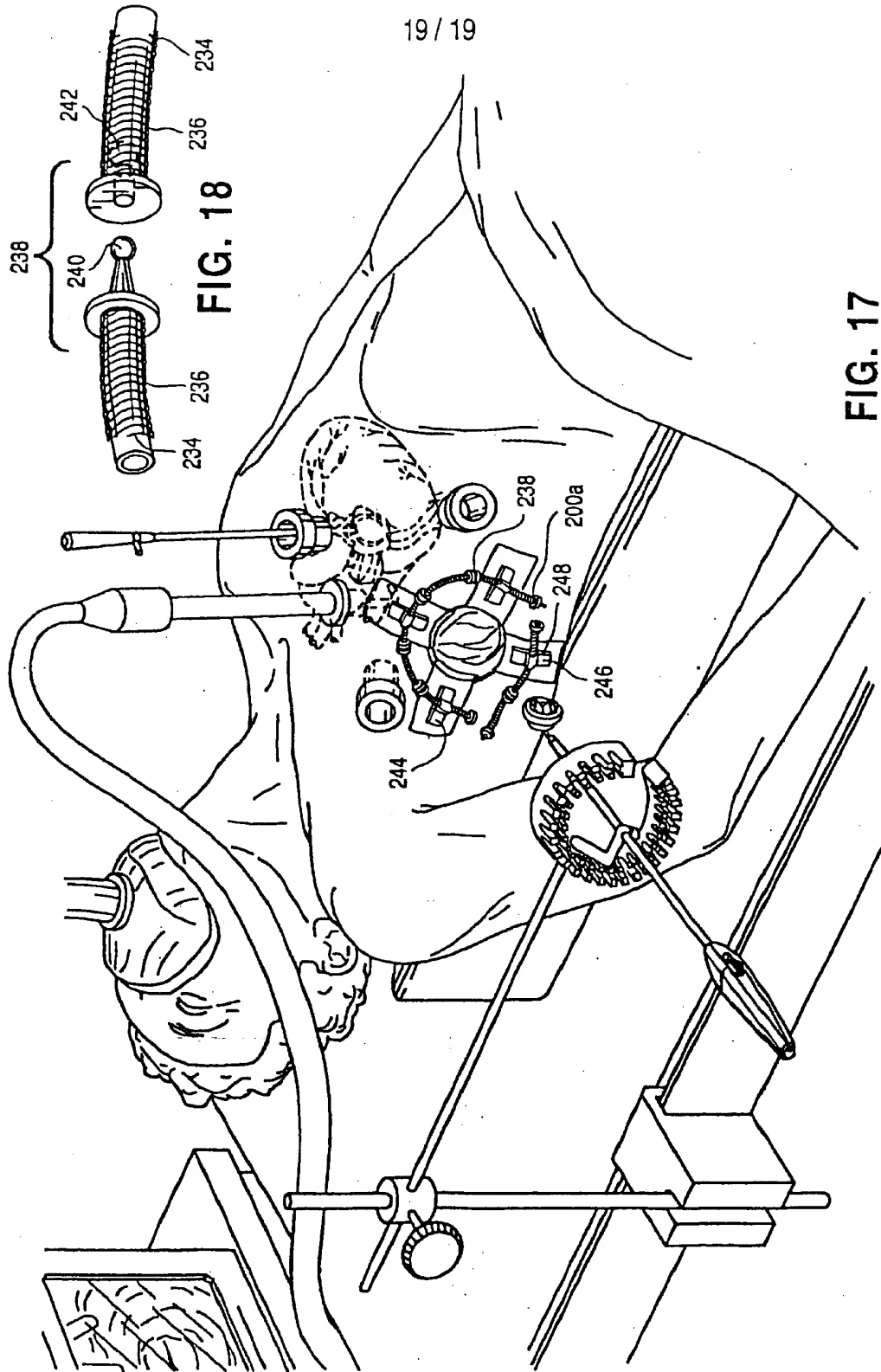
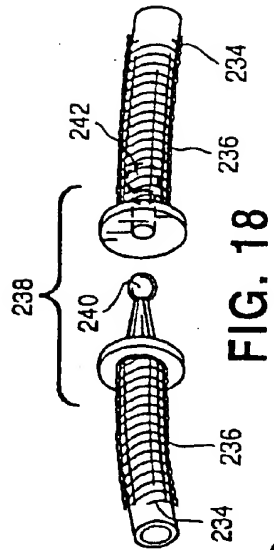


FIG. 17



**FIG. 18**